PATENT
071949-4102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kenneth F. Buechler et al.

Title: METHOD FOR MONITORING THE STATUS OF ASSAY AND IMMUNOASSAY

Appl. No.: 09/712,615

Filing Date: November 13, 2000

Examiner: Lisa V. Cook

Art Unit: 1641

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REPLY BRIEF

Mail Stop Appeal Brief - Patents
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Sir:

In reply to the Examiner's Answer mailed July 28, 2006, Applicants (herein, "Appellants") submit this Reply Brief regarding the Final Rejection of claims 27, 28, and 93-128. If any fee due is absent or incorrect, please charge or credit our Deposit Account No. 50-0872 for the appropriate amount.

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Argument

As the Examiner's Answer is, in all material respects, a repeat of the arguments made in the final Office Action, Appellants respectfully submit that the Examiner's Answer fails to consider arguments advanced by Appellants. As such, this Reply is being used to highlight key issues and evidence overlooked or ignored by the Examiner.

1. Rejection of Claims 27, 28, and 93-128 under 35 U.S.C. §112, second paragraph (definiteness)

The Examiner ignores or simply fails to apply the proper threshold for establishing indefiniteness. In the words of the Federal Circuit, the threshold is very high:

> The threshold for indefiniteness is very high: the claim must be "insolubly ambiguous". . . . If one of skill in the art would understand the scope of the claim when read in light of the specification, then the claim complies with § 112(2). Claims need not be models of clarity. As long as the meaning is discernible, then even if construction is difficult and the result equivocal, the claim is nevertheless definite. Exxon Research & Eng'g Co., 265 F.3d at 1375, 60 USPQ2d at 1276; All Dental Prodx LLC v. Advantage Dental Prods., Inc., 309 F.3d 774, 779-80, 64 USPQ2d 1945, 1949 (Fed. Cir. 2002) (no indefiniteness despite the lack of clarity).

Scripps Research Institute v. Nemerson, 78 U.S.P.Q.2d 1019, 1030 (BPAI 2005). When judged by this standard, it is clear that the present claims are not "insolubly ambiguous," and so meet the definiteness standard.

The Examiner asserts that the term "timing zone" is a "relative term" not defined in the claim. Examiner's Answer, page 3. The Examiner also asserts that "the relationship between the "assay zone" and the "timing zone" is not clear. *Id.*, page 4. The error in these assertions is an invalid and unreasonable interpretation of the term "timing zone" resulting from considering the term in isolation, rather than in the context provided by the rest of the claim and by the specification. An inspection of independent claim 27 exposes these errors in the Examiner's analysis.

Claim 27 is shown below with emphasis.

> 27. An apparatus for measuring progress and time of completion of an assay for an analyte, comprising:

(a) an assay device comprising:

(i) a reaction chamber comprising an optically detectable label, and

(ii) at least one diagnostic lane comprising at least one assay zone configured to bind said analyte and at least one timing zone separate from the assay zone, wherein said diagnostic lane is in fluid communication with said reaction chamber, and wherein, when fluid is added to said reaction chamber, said detectable label flows with said fluid to said at least one diagnostic lane to contact said at least one timing zone;

(b) an optical component configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response; and

(c) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

The "apparatus" of claim 27 has three elements: "an assay device" (section a), "an optical component" (section b), and "a signal processor" (section c). The "assay device" element has "at least one diagnostic lane comprising at least one assay zone configured to bind said analyte *and at least one timing zone separate from the assay zone.*" This portion of the claim informs the artisan that the "timing zone" is located on the diagnostic lane of an assay device, and that the "timing zone" is separate from "an assay zone configured to bind the analyte of interest."

If this portion of the claim is taken in isolation (as the Examiner has done), the term "timing zone" could be considered a bare reference to a location within an assay device. But this portion of the claim does not stand in isolation, and it is improper to ignore the additional context provided elsewhere in the claim. *See*, MPEP § 2173.02 ("the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope...").

Additional information in section (a) of the claim states that the "assay device" contains "an optically detectable label" in "a reaction chamber," and that the "assay device" is configured such that "when fluid is added to said reaction chamber, said detectable label flows with said fluid to said at least one diagnostic lane to contact said at least one timing zone." In addition,

section (b) states that the "optical component" element of the apparatus is "*configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response.*" From this information, the artisan understands that an optical signal from "an optically detectable label" flowing into the "diagnostic lane" is detected at the "timing zone," and "an electronic signal" is generated from that detection.

To complete the artisan's understanding, the claim then states in section (c) that the "signal processor" component of the apparatus is configured "*to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device*" from the characteristics of that "electronic signal." By reading the entire claim, the artisan is informed that a "timing zone" is a location within an assay device from which a signal is generated that is used by a signal processor to determine the progress and time of completion of the assay(s) for the analyte(s) of interest. The location is separate from the assay zone(s) that bind the analyte(s) of interest, and the signal is derived from a detectable label that flows from a reaction chamber to contact the timing zone.

This understanding of the term "timing zone" (as properly derived from a reading of the entire claim) is further reinforced by reference to the present specification. *See*, MPEP § 2173.02 (Definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the application's disclosure). Beginning on page 70, in the Example entitled "*Methods for Detecting the Completion of an Immunoassay Using IACs*," and particularly the discussion beginning on page 73, section entitled "*Use of the Timing Signal to Detect Assay Completion of Immunoassay Devices*," the use of timing zones and timing signals is described in detail. The phrase "timing zone," which can be found on page 71, line 3, refers to a zone within an assay device (separate from the assay "detection zones" of the device) where a signal is detected and used to determine if the assay for the analyte of interest has run to completion. Indeed, methods and devices for determining the progress and time of completion of assays using a signal obtained from such a "timing zone" are described in detail throughout the specification, *e.g.*, on page 13, line 7, through page 14, line 15; page 40, line 9, through page 42, line 23; page 70, line 15, through page 71, line 11; and page 73, line 6, through page 75, line 30.

When claim 27 is considered as a whole and read in light of the specification, the plain language of the claim indicates clearly to one skilled in the art what is meant by the "timing zone," and that meaning is consistent with the understanding that is provided by the specification. Moreover, when analyzed properly, it is also clear that the present claims are not "insolubly ambiguous."

In contrast, the Examiner asserts that the term "timing zone" should be considered a "relative term." Examiner's Answer, page 3. Apart from this bare assertion, no other information is provided. Relative terms are "terms of degree" that may be used in claim language. See MPEP § 2173.05(b). A bare assertion that a term is relative falls well below the threshold of establishing a *prima facie* rejection for indefiniteness.

The Examiner asserts that the claims are indefinite "because the interaction of the timing zone [with the assay zone?] is unclear." Examiner's Answer, page 4. The skilled artisan understands from the specification that the timing zone may be placed at the distal end of the diagnostic lane, which is described as a "preferred location." *See, e.g.*, specification, page 41, lines 11-15). But the Federal Circuit has cautioned against limiting a claimed invention to preferred embodiments or specific examples set forth in the specification. *See, e.g., Texas Instruments, Inc. v. U.S. Int'l Trade Comm.*, 805 F.2d 1558, 1562, 231 U.S.P.Q. 833, 835 (Fed. Cir. 1986). The specification describes that the timing zone is a "discrete zone" of the diagnostic lane, and thus may also be placed elsewhere such as parallel to or before the assay zone. The claim is not rendered indefinite simply because it is broad. *See*, MPEP § 2173.04. In addition, neither the claims nor the specification require that the label used to generate a signal at the timing zone be bound to the timing zone, as the Examiner apparently believes. For example, the specification describes that while binding of the label to the timing zone is one embodiment of the present invention, a signal may also be generated from label flowing *through* the timing zone. *See, e.g.*, specification, page 71, lines 4-6.

The fact that the rejection is not based on the proper standard by which definiteness is judged is further emphasized by the Examiner acknowledging that claims 97 and 98, which depend from independent claim 27, are not indefinite. These claims only further limit claim 27 by reciting that the label used at the timing zone binds to the timing zone. The fact that the

Examiner has deemed these claims allowable (if rewritten in independent form) exposes the hollowness of the reasoning underlying the indefiniteness rejection.

Because the definiteness requirement of 35 U.S.C. § 112, second paragraph, has been met, Appellants respectfully request that the rejection of claims 27, 28, and 93-128 be withdrawn or reversed.

2. Rejection of Claims 27, 28, and 93-128 under 35 U.S.C. § 112, first paragraph (written description)

The Examiner asserts a lack of written description support for the timing zone separated from the assay zone. Examiner's Answer, page 4. However, such support is found in an example where the timing zone is "downstream of the last detection zone;" by definition, such a timing zone is separate from the assay zone. *See, e.g.*, specification, page 71, lines 2-4. Moreover, the specification states that a timing zone signal is measured at "a discrete zone" in the diagnostic lane. *See, e.g.*, specification, page 13, lines 11-15; page 41, lines 6-10; and page 42, lines 2-4. The specification also states that the assay measurement may be made in one zone, and the "independent assay control" (or "IAC") signal (*e.g.*, the timing zone signal, which is an IAC as noted on page 70, in the Example entitled "*Methods for Detecting the Completion of an Immunoassay Using IACs*,") can be measured in another zone. *See, e.g.*, specification, page 12, line 30, through page 13, line 21. Inexplicably, the Examiner has neither acknowledged the above description nor explained why it is insufficient.

Moreover, as in the indefiniteness rejection discussed above, the Examiner's statement that claims 97 and 98 would be allowable if written in independent form exposes the hollowness of this rejection based on a lack of written description, as nothing added in claims 97 or 98 relates to the Examiner's reasoning in rejecting the claims.

In view of the clear teachings in the instant specification, Appellants respectfully submit that the skilled artisan is reasonably informed that Appellants were in possession of "an apparatus having at least one timing zone separated from the assay zone," the only written description basis on which the Examiner objects to the claims. Because the written description requirement of 35 U.S.C. § 112, first paragraph, demands no more, Appellants respectfully request that the rejection of claims 27, 28, and 93-128 be withdrawn or reversed.

3. Rejection of Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 under 35 U.S.C. § 103(a)

The Examiner's obviousness analysis is premised upon a fundamentally flawed understanding of the cited publications. First, the Examiner asserts that the primary Buechler '852 patent discloses "a time gate for measuring the reaction in a given period of time." Examiner's Answer, page 6 (emphasis added). This assertion, however, is not supported by the primary '852 patent. Column 7, lines 41-47 of the '852 patent defines a "time gate" as follows (emphasis added):

Time Gate

> Referring to FIG. 1a, the time gate 5 holds the reaction mixture in the reaction chamber 4 for a given period of time. The concept of the time gate is that a predominantly aqueous solution cannot pass through a hydrophobic zone until the hydrophobic zone is made hydrophilic. Furthermore, the hydrophobic zone is made hydrophilic by a component in the aqueous solution.

Thus, the "time gate" does not *measure* any reaction; rather, it is a device that *delays* flow across a hydrophobic zone until that zone is made hydrophilic. Nothing in the '852 patent discloses "a time gate for measuring the reaction in a given period of time" as the Examiner believes. Indeed, in the '852 patent, there is no signal generated from this "time gate." As such, there is no progress of an assay and its time of completion determined from a signal from the "time gate," and also no processor configured to receive and process such a signal, as required by the present claims.

Also fundamentally flawed is the Examiner's belief that the primary Buechler '852 patent is sufficient to meet various other elements of the present claims, because two claim limitations associated with "configured to" language are allegedly not material limitations of the claim. Examiner's Answer, pages 13 and 14 ("With respect to the language 'configured to detect', Applicant argues this represents structural elements that must be considered. However, the structural elements have not been included in the claims."). During prosecution, Appellants have repeatedly directed the Examiner's attention to decisions by the Board of Patent Appeals and Interferences stating that the recitation of elements as being "configured to" one another is

common in patents and represents structural limitations that must be considered. The Examiner however has chosen to ignore such decisions in maintaining the rejection.

When the structural elements that have been ignored by the Examiner are properly considered, it is apparent the '852 patent does not disclose or suggest any "optical component" configured to detect an optical signal generated from its "time gate" and generate an electronic signal in response. The '852 patent does not consider the "time gate" to be an element from which a signal either can or should be determined. Furthermore, because there is no signal to be generated from this "time gate," no "signal processor" is configured to determine the progress of an assay and its time of completion from a signal from the "time gate."

The Examiner's reliance on Van Deusen *et al.* '097 patent solely for disclosure of "an optical signal detector and signal processor" fails in this regard because the optical signal detector and signal processor must be configured in the manner claimed. No motivation is established to do so since the Examiner believes the "configured to" language is not material, and so ignores these structural limitations in the claims.

The publications of record, whether considered separately or together, do not disclose or suggest that any signal should be obtained from a discrete timing zone, or that a signal processor should be used to determine the progress and time of completion of an assay from that signal. Furthermore, the fundamental elements of an obviousness rejection -- a teaching or suggestion of each element of the claims and a motivation to modify the cited publications to provide the invention as claimed -- are lacking from the Examiner's asserted *prima facie* case.

Appellants request that the rejection of claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 under 35 U.S.C. § 103(a) be withdrawn or reversed.

4. Rejection of Claims 95 and 117 under 35 U.S.C. § 103(a)

This rejection fails for the same reasons discussed above. The tertiary reference provides no facts that would cure the deficiencies noted for the primary and secondary references, as the now-referenced Slovacek *et al.* publication is cited only for the disclosure of "a fluorometer as a useful optical detector." Examiner's Answer, page 7. Appellants therefore respectfully request that the rejection of claims 95 and 117 be withdrawn or reversed.

5. Rejection of Claims 28, 101, 102, 104, 107, 108, 127, and 128 under 35 U.S.C. § 103(a)

Similarly, this rejection fails for the same reasons discussed above. The tertiary reference provides no facts that would cure the deficiencies noted for the primary and secondary references, as the now-referenced Foster *et al.* publication is cited only for the disclosure of assays in kit form. Examiner's Answer, page 8.

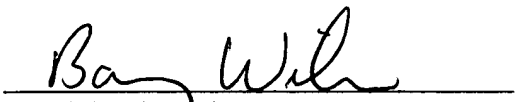
Appellants therefore respectfully request that the rejection of claims 95 and 117, and the rejection of claims 28, 101, 102, 104, 107, 108, 127, and 128, be withdrawn or reversed.

Conclusion

For the reasons discussed above, Appellants respectfully submit that claims 30, 31, and 42 claims are in condition for allowance, and respectfully request that the rejections be withdrawn or reversed, and that the claims be allowed to issue. Appellants further request that the remaining dependent claims be examined on their merits in view of the allowability of generic claim 30.

Respectfully submitted,

Date: August 31, 2006

By: 
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Appendix A: Text of the Claims Involved in the Appeal

Claims 1-26 (Cancelled)

27. (Previously presented) An apparatus for measuring progress and time of completion of an assay for an analyte, comprising:

(a) an assay device comprising:

(i) a reaction chamber comprising an optically detectable label, and

(ii) at least one diagnostic lane comprising at least one assay zone configured to bind said analyte and at least one timing zone separate from the assay zone, wherein said diagnostic lane is in fluid communication with said reaction chamber, and wherein, when fluid is added to said reaction chamber, said detectable label flows with said fluid to said at least one diagnostic lane to contact said at least one timing zone;

(b) an optical component configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response; and

(c) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

28. (Previously presented) A kit for measuring progress and time of completion of an assay for an analyte, comprising:

(a) at least one set of instructions for measuring said progress and time of completion; and

(b) an apparatus according to claim 27.

Claims 29-92 (Cancelled)

93. (Previously presented) The apparatus of claim 27, wherein said label is selected from the group of molecules consisting of dye, fluorescence emitting dye, chemiluminescence emitting

dye, infrared emitting dye, colloidal sol, molecule that generates an electrical signal, molecule that generates a magnetic signal, molecule that generates and electrical and magnetic signal, and enzyme.

94. (Previously presented) The apparatus of claim 27, wherein the assay device is an immunoassay device.

95. (Previously presented) The apparatus of claim 27, wherein the optical component is a fluorometer.

96. (Previously presented) The apparatus of claim 27, wherein the reaction chamber and said at least one diagnostic lane are each within a capillary space.

97. (Previously presented) The apparatus of claim 27, wherein the label is attached to a first member of a binding pair that binds to a second member of the binding pair that is bound to said at least one timing zone of said at least one diagnostic lane.

98. (Previously presented) The apparatus of claim 97, wherein one or both of said first and second members of the binding pair is an antibody.

99. (Previously presented) The apparatus of claim 27, wherein said signal processor determines the progress and time of completion of said assay in said device from the rate of change of the amount of signal.

100. (Previously presented) The apparatus of claim 27, wherein said signal processor determines the progress and time of completion of said assay in said device from the absolute amount of signal.

101. (Previously presented) The kit of claim 28, wherein said label is selected from the group of molecules consisting of dye, fluorescence emitting dye, chemiluminescence emitting dye, infrared emitting dye, colloidal sol, molecule that generates an electrical signal, molecule that generates a magnetic signal, molecule that generates and electrical and magnetic signal, and enzyme.

102. (Previously presented) The kit of claim 28, wherein the assay device is an immunoassay device.

103. (Previously presented) The kit of claim 28, wherein the optical component is a fluorometer.

104. (Previously presented) The kit of claim 28, wherein the reaction chamber and diagnostic lane are each within a capillary space.

105. (Previously presented) The kit of claim 28, wherein the label is attached to a first member of a binding pair that binds to a second member of the binding pair that is bound to said at least one timing zone of said at least one diagnostic lane.

106. (Previously presented) The kit of claim 105, wherein one or both of said first and second members of the binding pair is an antibody.

107. (Previously presented) The kit of claim 28, wherein said signal processor determines the progress and time of completion of said assay in said device from the rate of change of the amount of signal.

108. (Previously presented) The kit of claim 28, wherein said signal processor determines the progress and time of completion of said assay in said device from the absolute amount of signal.

109. (Previously presented) The apparatus of claim 27, wherein said at least one assay zone and said at least one timing zone are located in the same diagnostic lane.

110. (Previously presented) The apparatus of claim 27, wherein said at least one assay zone and said at least one timing zone are located in a separate diagnostic lane.

111. (Previously presented) The apparatus of claim 27, wherein a surface of said at least one timing zone is configured to bind said detectable label.

112. (Previously presented) The apparatus of claim 27, wherein said at least one assay zone does not appreciably bind said detectable label.

113. (Previously presented) An apparatus for measuring progress and time of completion of an assay for an analyte, comprising:

(a) an assay device comprising:

(i) a reaction chamber, and

(ii) at least one diagnostic lane comprising at least one assay zone configured to bind said analyte and at least one timing zone separate from the assay zone, wherein said diagnostic lane is in fluid communication with said reaction chamber, and wherein, when fluid and a detectable label are added to said reaction chamber, said detectable label flows with said fluid to said at least one diagnostic lane to contact said at least one timing zone;

(b) an optical component configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response; and

(c) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

114. (Previously presented) The apparatus of claim 113, wherein said apparatus further comprises said detectable label.

115. (Previously presented) The apparatus of claim 114, wherein said label is selected from the group of molecules consisting of dye, fluorescence emitting dye, chemiluminescence emitting dye, infrared emitting dye, colloidal sol, molecule that generates an electrical signal, molecule that generates a magnetic signal, molecule that generates and electrical and magnetic signal, and enzyme.

116. (Previously presented) The apparatus of claim 113, wherein the assay device is an immunoassay device.

117. (Previously presented) The apparatus of claim 113, wherein the optical component is a fluorometer.

118. (Previously presented) The apparatus of claim 113, wherein the reaction chamber and said at least one diagnostic lane are each within a capillary space.

119. (Previously presented) The apparatus of claim 113, wherein the label is attached to a first member of a binding pair that binds to a second member of the binding pair that is bound to said at least one timing zone of said at least one diagnostic lane.

120. (Previously presented) The apparatus of claim 119, wherein one or both of said first and second members of the binding pair is an antibody.

121. (Previously presented) The apparatus of claim 113, wherein said signal processor determines the progress and time of completion of said assay in said device from the rate of change of the amount of signal.

122. (Previously presented) The apparatus of claim 113, wherein said signal processor determines the progress and time of completion of said assay in said device from the absolute amount of signal.

123. (Previously presented) The apparatus of claim 113, wherein said at least one assay zone and said at least one timing zone are located in the same diagnostic lane.

124. (Previously presented) The apparatus of claim 113, wherein said at least one assay zone and said at least one timing zone are located in a separate diagnostic lane.

125. (Previously presented) The apparatus of claim 113, wherein a surface of said at least one timing zone is configured to bind said detectable label.

126. (Previously presented) The apparatus of claim 113, wherein said at least one assay zone does not appreciably bind said detectable label.

127. (Previously presented) A kit for measuring progress and time of completion of an assay for an analyte, comprising:

(a) at least one set of instructions for measuring said progress and time of completion; and

(b) an apparatus according to claim 113.

128. (Previously presented) A kit for measuring progress and time of completion of an assay for an analyte, comprising:

(a) at least one set of instructions for measuring said progress and time of completion; and

(b) an apparatus according to claim 114.

Appendix B: Evidence Appendix

1. *Scripps Research Institute v. Nemerson*, 78 U.S.P.Q. 2d 1019 (Bd. Pat. App. & Interf. 2005) **(attached herewith as Exhibit A)**

2. *Texas Instruments v. U.S. Int'l Trade Comm.*, 805 F.2d 1558, 231 U.S.P.Q. 833 (Fed. Cir. 1986) **(attached herewith as Exhibit B)**

3. Buechler, U.S. Patent 5,458,852, cited by the Examiner in Office Action mailed August 24, 2001

4. Van Deusen *et al.*, U.S. Patent 5,132,097, cited by the Examiner in Office Action mailed August 24, 2001

5. Slovacek *et al.*, U.S. Patent 5,242,837, cited by the Examiner in Office Action mailed August 24, 2001

6. Foster *et al.*, U.S. Patent 4,444,879, cited by the Examiner in Office Action mailed November 24, 2003

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Scripps Research Institute
v.
Nemerson

U.S. Patent and Trademark Office Board of Patent Appeals and Interferences

Interference No. 105,128

Decided February 17, 2005

PATENTS

[1] Patentability/Validity -- Date of invention -- Reduction to practice (§ 115.0405)
Patentability/Validity -- Specification -- Written description (§ 115.1103)

Junior party in interference has failed to demonstrate that senior party should be denied benefit date of its prior application on ground that application does not provide adequate written description of invention of count, which is directed to soluble portion of human tissue factor protein having specific amino acid sequence, since polypeptide represented by amino acid residues of formula in benefit application appear to be identical to those required by count, since level of skill required to appreciate this teaching would have been well within ordinary level of skill in art at relevant time, and since testimony of junior party's expert focuses on whether senior party actually possessed polypeptide of count, and whether application described method of producing peptide, but does not state that person of ordinary skill in art would not have understood senior party to have described invention of count.

[2] Patentability/Validity -- Date of invention -- Reduction to practice (§ 115.0405)
Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Junior party in interference has failed to demonstrate that senior party should be denied benefit date of its prior application on ground that application does not enable invention of count, which is directed to soluble portion of human tissue factor protein having specific amino acid sequence, since senior party's expert testified that person of skill in art would have known how to make hTF fragment of count from full-length hTF using restriction enzyme, and his testimony is credible and largely unrebutted, since "motivation" to make invention is not requirement for enablement, since breadth of count has little relevance, in that scope of enablement is limited to scope of single embodiment relied on to establish priority, since restriction-enzyme approach was routine at time of invention, and there is no evidence that it would have been considered unpredictable, and since, with guidance of prior art, including senior party's prior application, production and use of claimed hTF fragment appears to have required no more than routine experimentation.

[3] Patentability/Validity -- Date of invention -- Reduction to practice (§ 115.0405)
Patentability/Validity -- Specification -- Best mode (§ 115.1107)

Junior party in interference has failed to demonstrate that senior party should be denied benefit date of its prior application on ground that application does not disclose best mode for making and using invention of count, which is directed to soluble portion of human tissue factor protein having specific amino acid sequence, since junior party has not shown that there is best-mode requirement for constructive reduction to practice, since enablement and best mode are distinct requirements, and junior party therefore cannot establish that senior party had undisclosed best mode in mind, at time of filing of benefit application, based solely on allegation that no mode was described or enabled, and since priority application disclosed modes of both making and using invention.

[4] Patentability/Validity -- Specification -- Claim adequacy (§ 115.1109)

Junior party in interference has failed to demonstrate that senior party's application claim corresponding to count, which is directed to soluble portion of human tissue factor protein having specific amino acid sequence, is unpatentable for indefiniteness on ground that it is directed to cloning vector that will not necessarily express recombinant protein as claim requires, since specification teaches difference between expression vector and nonexpressing cloning vector, and junior party has not shown that nonexpressing cloning vectors could not have been screened out using routine skill, since junior party's contentions that claim is overbroad go to issue of enablement rather than indefiniteness, since mathematical precision in claim is not required if person of skill in art could have determined its scope, since, even if protein-expression host systems are not entirely predictable, there is no evidence that ordinary artisan, after reading specification, would have been daunted by task of making or using

invention, since functional limitation in claim does not necessarily correspond to any specific structure, but is not per se indefinite, and since testimony that wide range of vectors might be used in invention does not prove that person skilled in art would consider claim insolubly ambiguous or unduly challenging to put into practice.

[5] Practice and procedure in Patent and Trademark Office -- Interference -- Rules and rules practice (§ 110.1704)

Patentability/Validity -- Specification -- Claim adequacy (§ 115.1109)

Board of Patent Appeals and Interferences, in case in which senior party's application claim refers to nonexistent "Figure I," will defer decision on whether claim is unpatentable for indefiniteness, since, if claim is read in context of specification and other claims, need to correct "Figure" to "Formula" is readily apparent; senior party will therefore be given 30 days to file amendment changing "Figure I" to "Formula I," and failure to do so will result in automatic grant of junior party's motion to hold claim indefinite.

[6] Practice and procedure in Patent and Trademark Office -- Interference -- Evidence (§ 110.1709)

Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Expert declarations submitted by junior party in interference for purpose of establishing that there was much uncertainty in relevant art in 1987 when senior party's parent application was filed do not constitute evidence that claims in senior party's involved application, which was filed in 1995, are unpatentable for failure to satisfy enablement requirement of 35 U.S.C. § 112, since, in absence of intervening prior art, whether parent application adequately complies with enablement requirement is not determinative of patentability of "child" application.

[7] Patentability/Validity -- Construction of claims (§ 115.03)

Patent construction -- Claims -- Broad or narrow (§ 125.1303)

Dependent claim in application directed to soluble portion of human tissue factor protein having specific amino acid sequence, which recites fragment of hTF protein "having a portion of the amino acid sequence shown in Formula I," is not improper dependent claim, since use of "having" does not create presumption that limitation is open-ended, and since dependent claim, read in context, further limits hTF fragment of independent claim to relevant portions of referenced formula; however, dependent claim that is open to encoding through amino acid residue 242, which is apparently all of transmembrane domain, is unpatentable as improper dependent claim, since independent claim "includes none or part of" transmembrane domain, which is defined in application as "comprising approximately amino acids 220 to 242."

[8] Practice and procedure in Patent and Trademark Office -- Interference -- Rules and rules practice (§ 110.1704)

Patentability/Validity -- Construction of claims (§ 115.03)

Patent construction -- Claims -- Broad or narrow (§ 125.1303)

Dependent claim in senior party's application directed to soluble portion of human tissue factor protein having specific amino acid sequence, which is broader than claim from which it depends, is unpatentable as improper dependent claim, and senior party will not be permitted to amend claim during interference, since proper time for party to amend claim is in response to motion that brings defect to light, and senior party was provided with opportunity to amend claims during earlier time period but failed to do so, and since senior party's error is not amenable to simple correction.

[9] Patentability/Validity -- Construction of claims (§ 115.03)

Patent construction -- Claims -- Broad or narrow (§ 125.1303)

Dependent claims in application directed to soluble portion of human tissue factor protein having specific amino acid sequence do not improperly broaden claim from which they depend, even though dependent claims employ term "comprises," since independent claim offers Markush group of alternatives for claimed hTF protein fragment, and Markush group is by its nature "closed," since language of exclusion and use of term "consisting of" in Markush alternatives create relatively closed context in which dependent claims must be construed, and since dependent claims in this context cannot reasonably be read to include matter already excluded by independent claim.

[10] Patentability/Validity -- Specification -- Written description (§ 115.1103)

Written description that merely renders claimed invention obvious is not sufficient to satisfy written description requirement, and if disclosure is said to be inherent, then missing descriptive matter must necessarily be present in specification such that person of skill in art would recognize such disclosure; in present interference, senior party's claims in application directed to soluble portion of human tissue factor protein having specific amino acid sequence, in which soluble hTF is defined in

terms of being expressed from polynucleotide that can encode amino acid residues 1-209 shown in figure in application, are not supported by adequate written description, since specification does not expressly describe creation of fragment encompassing residues 1-209, since referenced figure shows entire hTF gene encoding entire hTF protein, including its signal sequence, and since senior party argues that person of skill in art would have been able to use computers and restriction enzymes to cleave polynucleotide at "appropriate" sites, but has not shown that cleavage at single methionine residue in protein would necessarily produce 1-209 residue hTF fragment.

[11] Patentability/Validity -- Specification -- Written description (§ 115.1103)

Claim in application directed to soluble portion of human tissue factor protein having specific amino acid sequence, which identifies protein fragment that terminates at approximately amino acid residues 219/220 as shown in figure in application, is supported by adequate written description, even though application disclosure is open-ended, in that it identifies soluble fragment as "compris[ing] the extracellular domain," since written description specifically discloses recited embodiments, and since person of skill in art would have understood application to disclose at least those embodiments with explicitly recited endpoints, and would have understood "approximately amino acids 219/220" as explicitly identifying at least embodiments 1-219 and 1-220.

[12] Patentability/Validity -- Specification -- Written description (§ 115.1103)

Claim in application directed to soluble portion of human tissue factor protein having specific amino acid sequence, which recites "truncated" hTF protein expressed from polynucleotide molecule encoding amino acid sequence from amino acid residues 1-227 identified in figure in application, is supported by adequate written description, even though "truncated" hTF is described as lacking last 37 residues, which would result in fragment having residues 1-226, since application does not expressly or constructively disavow 1-227 residue embodiment of invention, and expressly teaches expressed 1-227 residue embodiment, and since, even if portions of specification can be considered inconsistent with such embodiment, there is no "teaching away" concept for written description requirement short of express disavowal of subject matter.

[13] Patentability/Validity -- Specification -- Written description (§ 115.1103)

Claim in senior party's application directed to soluble portion of human tissue factor protein having specific amino acid sequence, which recites hTF protein expressed from polynucleotide molecule encoding amino acid sequence shown in figure in application, but with amino acid residues 220 to 224 omitted, is not supported by adequate written description, since application teaches that residues 220-242 define transmembrane domain, but does not include written description of otherwise complete hTF protein that lacks transmembrane domain residues, and since senior party has not explained how person of skill in art would understand claimed protein fragment to be disclosed either explicitly or implicitly.

[14] Patentability/Validity -- Specification -- Written description (§ 115.1103)

Claim in senior party's involved application, which recites human tissue factor protein expressed in recombinant nonhuman host from polynucleotide molecule encoding amino acid sequence "comprising" amino acid residues 1-219 shown in figure in application, is supported by adequate written description, even though "comprising" transition opens scope of claim, since it does so only with respect to range of recited residues, since conclusion that claim would include full-length hTF protein, which is explicitly disclosed in specification, does not support finding that claim lacks adequate written description, and since range of possible hosts claimed is very broad, but specification discloses such hosts broadly.

[15] Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Junior party in interference has failed to demonstrate that claims in senior party's application, which is directed to soluble portion of human tissue factor protein having specific amino acid sequence, are unpatentable for failure to satisfy enablement requirement of 35 U.S.C. § 112, since disclosure is presumed to be enabled, and since junior party has not shown that cited deficiencies in claims, including alleged vagueness of certain claim terms, scope of terms, and scope of claims themselves, would render invention impossible to use without undue experimentation.

[16] Practice and procedure in Patent and Trademark Office -- Interference -- Rules and rules practice (§ 110.1704)

Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Senior party in interference has failed to demonstrate that claims in junior party's patent, which is directed to soluble portion of human tissue factor protein having specific amino acid sequence, are unpatentable for failure to satisfy enablement requirement of 35 U.S.C. § 112, since senior party's

blanket citation to evidence is unacceptable practice, since senior party's evidence, which is directed to state of art in 1987, does not show what person skilled in art would have understood about sufficiency of enablement of subject matter of claims in 1992 when junior party's patent application was filed, and since, even if it is assumed that disclosed process is laborious and time-consuming, that fact alone would not render invention impossible to use without undue experimentation.

[17] Patentability/Validity -- Date of invention -- Conception (§ 115.0403)

Patentability/Validity -- Inventorship (§ 115.13)

Senior party in interference has failed to demonstrate that claim in junior party's patent, which is directed to soluble portion of human tissue factor protein having specific amino acid sequence, is unpatentable for failure to name alleged co-inventor, since, even if it is assumed that contribution of individual in question was necessary for conception of invention by named inventors, it does not automatically follow that individual qualifies as co-inventor, and since there is no evidence that individual contributed to actual conception of invention defined in claim.

***1023** Patent interference between Scripps Research Institute, junior party (patent no. 5,622,931) and Yale Nemerson and William H. Konigsberg, senior party (application serial nos. 08/297,581 and 08/473,262). On junior party's preliminary motions attacking filing date benefit accorded senior party, and attacking patentability of claims in senior party's involved applications, and on senior party's preliminary motions attacking enablement and inventorship of junior party's involved claims. Junior party's motion attacking benefit denied; motions attacking patentability granted in part, deferred in part, and denied in part. Senior party's motions denied.

Related decision: 77 USPQ2d 1809.

[Editor's Note: The Board of Patent Appeals and Interferences has indicated that this opinion is not binding precedent of the board.]

Talivaldis Cepuritis and Dolores T. Kenney, of Olson &Hierl, Chicago, Ill., for junior party.

Patrea L. Pabst, of Pabst Patent Group, Atlanta, Ga., for senior party.

Before Torczon, Medley, and Poteate, administrative patent judges. [FN1]

Torczon, J.

DECISION - Bd. R. 125 - ON MOTIONS

INTRODUCTION

This interference is about priority of invention for the soluble portion of human tissue factor [hTF] protein with a specific amino acid sequence. The junior party, Scripps, has filed three motions:

Motion 1 attacking the benefit accorded to senior party Nemerson (Paper 63);

Motion 2 attacking the patentability of Nemerson's 08/473,262 [262] application claims (Paper 64); and

Motion 3 attacking the patentability of Nemerson's 08/297,581 [581] application claims (Paper 65).

Nemerson has two motions before us:

Motion 5 attacking the enablement of both of Scripps' 5,622,931 [931] patent claims (Paper 40); and

Motion 6 attacking the inventorship of Scripps' 931 claims (Paper 41).

FINDINGS OF FACT

The following findings are supported by at least a preponderance of the evidence. For each motion, the movant bears the ultimate burden of proof for the relief requested. Bd. ***1024** R. 121(b); *Velander v. Garner*, 348 F.3d 1359, 1369-70, 68 USPQ2d 1769, 1777 (Fed. Cir. 2003).

The count

[1] The sole count of the interference is (Paper 1 at 4):

A composition of claim 1 of the 5,622,931 patent.

[2] Claim 1 of the 931 patent is [3009 [FN2]]:

1. A composition comprising an aqueous solution of human tissue factor heavy chain protein wherein said protein is soluble and has an amino acid residue sequence represented by FIG. *1* from position 1 to position 219.

[3] The amino acid residues of 931 patent FIG. *1* are [3009]:

```
                -30         -20         -10
       ME TPAWPRVPRP ETAVARTLLL GWVFAQVAGA

        10          20          30          40
SGTTNTVAAY NLTWKSTNFK TILEWEPKPV NQVYTVQIST

        50          60          70          80
KSGDWKSKCF YTTDTECDLT DEIVKDVKQT YLARVFSYPA

        90         100         110         120
GNVESTGSAG EPLYENSPEF TPYLETNLGQ PTIQSFEQVG

       130         140         150         160
TKVNVTVEDE RTLVRRNNTF LSLRDVFGKD LIYTLYYWKS

       170         180         190         200
SSSGKKTAKT NTNEFLIDVD KGENYCFSVQ AVIPSRTVNR

       210         220         230         240
KSTDSPVECM GQEKGEFREI FYIIGAVVFV VIILVIILAI

       250         260
SLHKCRKAGV GQSWKENSPL NVS
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The junior party

[4] Scripps is involved in the interference on the basis of a patent (Paper 1 at 3):

T.S. Edgington & J.H. Morrissey, "Human tissue factor related DNA segments, polypeptides and antibodies", 5,622,931 (issued 22 April 1997).

[5] The 931 patent issued from the 07/880,079 [079] application, filed 29 April 1992.

[6] Scripps was further accorded the benefit (Paper 1 at 3) of:

07/165,939 [939] (filed 9 March 1988) (issued as 5,223,427), and

07/067,103 [103] (filed 25 June 1987) (issued as 5,110,730).

[7] The 931 patent has two claims (1 and 2), both of which have been designated (Paper 1 at 4) as corresponding to the count.

The senior party

[8] Nemerson is involved in the interference on the basis of two applications (Paper 1 at 3):

Y. Nemerson & W.H. Konigsberg, "Cloning and expression of human tissue factor", 08/297,581 (filed 29 August 1994);and

Y. Nemerson & W.H. Konigsberg, "Cloning and expression of human tissue factor", 08/473,262 (filed 7 June 1995).

[9] Nemerson was accorded the benefit (Paper 1 at 3) of:

07/732,991 (filed 18 July 1991),

07/632,616 (filed 26 December 1990),

07/208,895 (filed 17 June 1988),

07/167,870 (filed 14 March 1988), and

07/062,166 [166] (filed 12 June 1987) [3017].

[10] Nemerson's 581 claims 15, 42, 43, and 45-48 have been designated (Paper 1 at 4) as corresponding to the count.

[11] All of Nemerson's 262 claims (29-31, 33, 34, 36-39, and 44) have been designated (Paper 1 at 4) as corresponding to the count.

Scripps preliminary motion 1: attacking Nemerson's

accorded benefit

[12] Scripps attacks the presumption that Nemerson is entitled to the benefit for the purposes of priority in an interference of its 166 application (Paper 63).

[13] Scripps maintains (Paper 63 at 9) that:

[N]either Nemerson '581 nor Nemerson '262 is entitled to the benefit of the filing date of Nemerson 166 for the reason that Nemerson 166 does not constitute a constructive reduction to practice of any species encompassed by the subject matter of the Count as required by 37 C.F.R. § 1.637(f).

The rule prescribing the content of a motion attacking benefit at the time the motion was filed was 37 C.F.R. § 1.637(g), not § 1.637(f) (which relates to a motion seeking benefit). Although the underlying test for benefit is the ***1025** same whether it is sought or attacked, we shall apply [FN3] § 1.637(g), which succinctly required:

A preliminary motion to attack benefit under § 1.633(g) shall explain, as to each count, why an opponent should not be accorded the benefit of the filing date of the earlier application.

While the test for benefit in an interference is usually phrased in terms of § 112(1), it differs from that statute in at least one important regard: benefit only requires a single embodiment within the scope of the count. *Hunt v. Treppschuh*, 523 F.2d 1386, 1389, 187 USPQ 426, 429 (CCPA 1975).

[14] There is only a single count for which Scripps provides three lines of attack, paralleling the three requirements of 35 U.S.C. 112(1): written description, enablement, and best mode.

Uncontested facts

[15] The count excludes the transmembrane domain of hTF (Paper 63, Fact 9; admitted in Paper 59 [FN4] at 3).

[16] The invention described in the 166 application is directed to recombinant vectors and cDNA [FN5] for encoding the complete hTF apoprotein [FN6] (Paper 63, Facts 12 & 13; admitted in Paper 59 at 3).

[17] Neither a recombinant vector nor a cDNA is a protein (Paper 63, Facts 15 & 16; admitted in Paper 59 at 3).

[18] The 166 application generally discusses the structural and functional characteristics of full-length hTF and proposes a four-domain structure for hTF protein (Paper 63, Fact 19; admitted in Paper 59 at 3).

[19] Example 2 of the 166 application is directed to hybridization probes for DNA encoding polypeptides shorter than 219 amino acid residues (Paper 63, Fact 25; admitted in Paper 59 at 4).

[20] Example 5 of the 166 application describes a recombinant vector containing the cDNA for encoding the full-length hTF (Paper 63, Fact 27; admitted in Paper 59 at 4).

[21] Nemerson filed an information disclosure statement in the 166 application directed to full-length hTF and distinguishing a reference disclosing fragmentary sequences of hTF protein (Paper 63, Facts 28-30; admitted in Paper 59 at 4).

[22] The 166 application does not provide an example of, or a claim to, an aqueous solution of soluble hTF protein having the sequence specified in the count (Paper 63, Facts 31 & 32; admitted in Paper 59 at 4).

[23] The 166 application does include a claim to a vector containing cDNA for encoding full-length hTF protein (Paper 63, Fact 25; admitted in Paper 59 at 4).

Level of skill in the art

[24] The parties cannot agree on the level of skill in the art (compare Paper 63, Fact 34, neither admitted nor denied at Paper 59 at 4 with Paper 59, Facts 2, 8, 10, 11-15, variously either admitted or neither admitted nor denied in Paper 70 at 2).

[25] Scripps' characterization of the skill in the art as "relatively high, [but] the art is unpredictable" (Paper 63, Fact 34, references to the record omitted) is typical in patent practice, but not very helpful. [FN7]

[26] One skilled in the art would have known that nucleic acid sequence dictates the amino acid sequence of the protein expressed from the nucleic acid sequence (Paper 59, Fact 12, admitted in Paper 70 at 2).

[27] One skilled in the art would have believed in 1987 that hTF had procoagulant activity (Paper 59, Fact 13, admitted in Paper 70 at 2).

Additional findings on written description

[28] The 166 application discloses [3017 at 14:1-14, emphasis added] a soluble tissue factor protein

termination at approximately residue 219:

***1026** Soluble tissue factor, such as that portion of the protein encompassing the extracellular domain, is also preparable by DNA cloning techniques. A suitable cloned cDNA deletion mutant of the tissue factor gene generated, for example, by site specific mutagenesis, may be used to produce *a soluble tissue factor protein having a carboxy terminus at approximately amino acid 219* of the sequence provided in Formula I. [Description of a 1-210 residue alternative omitted.] Such soluble active tissue factor proteins would be extremely useful in clinical situations and as diagnostics for clotting disorders.

[1] [29] Formula I of the 166 application [3017 at 25]is "[t]he defined sequence of the substantially pure human factor" [3017 at 13:21-22].

[30] Polypeptides are numbered from their amino terminus to their carboxy terminus.

[31] A polypeptide that terminates at its approximately residue 219 of its carboxy terminus would be understood, absent other indicia, to include residues 1 through approximately 219.

[32] The small genus of polypeptides from residues 1 through approximately 219 expressly includes the species with residues 1-219.

[33] The polypeptide represented by residues 1-219 of Formula I appear to be identical to those required in the count.

[34] The level of skill required to appreciate this teaching would have been well within the ordinary level of skill in the art by 1987.

[35] Scripps relies on the expert testimony of Dr. Gerald Joyce, M.D., Ph.D., for the proposition [3025, ¶ 41, emphasis added] that:

The general descriptions of Nemerson '166 would not have conveyed in 1987 to a molecular biologist of ordinary skill *the existence of* a soluble human tissue factor protein having only amino acid residues 1-219.

Dr. Joyce, also states [3025, ¶ 47, emphasis added] that:

The specification of Nemerson '166 *does not describe the expression of* the extracellular domain of the tissue factor protein.

[36] Dr. Joyce's declaration focuses on whether Nemerson actually had the polypeptide of the count and described a method of producing the peptide rather than addressing the distinct, but more relevant, question of whether Nemerson described the invention of the count itself.

[37] We do not understand Dr. Joyce to have declared that one skilled in the art would not have understood Nemerson to have described the invention of the count.

[38] To the extent Dr. Joyce did declare that Nemerson did not describe the invention of the count, his testimony is without basis and is not credible.

[39] One skilled in the art would have appreciated that Nemerson's 166 application described the invention of the count.

Additional findings on enablement

[40] Scripps argues (Paper 63 at 12) that Nemerson failed to provide any enabled embodiments within the scope of the count.

Any constructive reduction to practice of the subject matter of the count must have been enabled at the time the disclosure was filed. To be enabling, the specification must have been sufficient to teach one skilled in the art how to make and use the invention without undue experimentation. There is no set list of factors for determining undue experimentation, *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991), but the determinative factors can usually be found in the list called "Forman" or "Wands" factors, [FN8] *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Which factors are relevant depends on the facts of the case. *Amgen, Inc.*, 927 F.2d at 1213, 18 USPQ2d at 1027.

[2] [41] Scripps argues that Nemerson failed to show how to make a soluble hTF with residues 1-219, or a solution containing such a protein, rather than a full-length hTF (Paper 63 at 12-13).

[42] Scripps notes that none of Nemerson's labeled examples are directed to the subject matter of the count (Paper 63 at 13-14).

A specification need not contain a working example if the invention is otherwise disclosed so that one skilled in the art would have been able to make and use the invention without undue experimentation. *In*

re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

***1027** [43] Nemerson relies on the declaration of Dr. Ronald R. Bach to show that one of skill in the art would have known how to make a 1-219 residue soluble hTF from full-length hTF using a restriction enzyme (Paper 59 at 14).

[44] Dr. Bach stated [2087, ¶ 6]:

The full nucleic acid sequence encoding full length human tissue factor was disclosed in the '166 patent application. With the full nucleic acid sequence in hand, it would have been routine for one of skill in the art in 1987 to analyze the sequence with computer software and generate a table listing the appropriate sites recognized by restriction enzymes and correlation to the final amino acid sequence. Such reports were standard practice when sequencing nucleic acid sequences in 1987. Computer reports such as these identified for example the unique SspI restriction site [for the SspI restriction enzyme] that cleaves the nucleic [acid] sequence at the necessary location to create a DNA fragment to express tissue factor 1-219. One of skill in the art in 1987 would have been fully capable of selecting the appropriate restriction enzyme, cleaving the cDNA sequence and expressing the sequence in commercially available expression systems to generate a truncated tissue factor.

[45] Dr. Bach's testimony regarding the ability in the art to make a 1-219 residue hTF is credible and largely unrebutted.

[46] Nemerson also points to subsequent success using the SspI protocol (Paper 59 at 15).

While a subsequent failure by an inventor to reduce an invention to actual practice may be probative of non-enablement, *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1376, 52 USPQ2d 1129, 1139 (Fed. Cir. 1999), subsequent success is not equivalently probative of enablement since it begs such questions as whether the inventor succeeded using only ordinary skill in the art, whether the inventor benefitted from undisclosed know-how, and whether the inventor was simply lucky.

[47] Scripps contends that one skilled in the art in 1987 would not have had any motivation to so cleave the full-length hTF (Paper 70 at 7).

[48] Scripps does not explain how case law requires motivation for enablement of an embodiment that is expressly described in the 166 application.

While the analyses for enablement and obviousness have much in common (e.g., they both permit supplementation of a basic teaching using what was known in the relevant art), motivation to make the invention is not a requirement for enablement. For enablement, the "motivation" to make and use the invention comes from the specification itself.

[49] Scripps argues that the relevant art was highly unpredictable, citing declarations from Dr. Nemerson [3016], Dr. Konigsberg [3014], and Dr. Joyce [3025] (Paper 63 at 14-15).

[50] Drs. Nemerson and Konigsberg are the Nemerson inventors.

[51] Exhibits 3014 and 3016 appear to be submissions from a European Patent Office opposition proceeding.

[52] While exhibits 3014 and 3016 indicate that much was uncertain in the art, neither discusses what one skilled in the art would have known or been able to do using the 166 application as a template.

Since the declarations of Drs. Nemerson and Konigsberg appear to address the state of the art without the relevant Nemerson disclosures, they are entitled to little weight in evaluating what one of skill would have considered the amount of experimentation necessary to make a 1-219 residue hTF after reading the 166 application. The putative fact that it would be hard to produce a necessary precursor--full-length hTF--without Nemerson's disclosure say little about how difficult it would be to produce 1-219 residue hTF with the guidance the disclosure provides, including disclosure of the full-length hTF.

[53] Scripps relies on the declaration of Dr. Joyce for the proposition that host cells have different codon preferences that can affect protein expression efficiency (Paper 63 at 14); [3025, ¶ 31].

[54] Dr. Joyce's testimony does not explain why codon-preference would have given one skilled in the art any pause.

[55] Scripps has not shown that one skilled in that art at the time would not have been aware of codon preferences and, if aware, would not have been aware of ways to mitigate or otherwise resolve the problem,

such as by selecting the host with the known codons of Nemerson's Formula I in mind.

[56] Scripps relies (Paper 63 at 14-15) on the 166 application itself to show that coagulation cascades were not fully understood.

[57] The 166 application does teach that the cascades are not fully understood, but nevertheless teaches the desirability of hTF generally ***1028** and soluble hTF specifically [3017 at 13:24-14:14].

[58] Scripps also argues that coagulation activity is not inherent in 1-219 residue hTF (Paper 63 at 15), citing the declaration of Dr. Sriram Krishnaswamy [3003, ¶¶ 15-16].

[59] Dr. Krishnaswamy states [3003]:

14. TF (1-219) alone does not initiate blood coagulation.

15. To initiate blood coagulation, a certain pre-existing amount of Factor VIIa must be present together with TF(1-219).

16. Coagulation activity is not inherent in TF(1-219), but is dependent upon the concentration of Factor VIIa that is present in the plasma to be assayed.

[60] Dr. Krishnaswamy does not declare that discovering the necessary concentration would require anything more than routine experimentation.

[61] The 166 application directs the reader "to test the procoagulant activity of soluble tissue factor with factor VII using either factors IX or X as substrates" [3017 at 13:25-27].

[62] Scripps relies on Wands factors 1-3 and 5-8 (Paper 63 at 15-16).

[63] With regard to Factor 8, Scripps argues that the count is broad (Paper 63 at 15).

Regardless of how broad the count may be, Nemerson only has to provide a single embodiment to be accorded benefit for the count. Consequently, the scope of enablement is limited to the scope of whatever disclosure Nemerson is trying use to establish priority. Nemerson is relying on a single embodiment, so only that embodiment need be enabled for the purposes of this motion. In this context, Factor 8 has little relevance.

[64] With regard to Factor 3, Scripps points to the lack of a working example (Paper 63 at 15).

As noted above, however, a working example is not a requirement. *Borokowski*, 422 F.2d at 908, 164 USPQ at 645. In the present case, we credit Dr. Bach's testimony that preparing a 1-219 residue hTF from the full-length hTF cDNA using the restriction enzyme Ssp I would have been routine.

[65] With regard to Factor 2, Scripps argues that the specification provides no guidance on how to make a truncated hTF (Paper 63 at 15).

[66] In fact, as shown above, the 166 provides guidance for making truncated hTF, including specifically 1-219 residue hTF.

[67] The 166 application does not provide the method, or the level of detail, for making 1-219 residue hTF that Dr. Bach provides.

An application is not intended to be a production specification and need not detail what is already known in the art. *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941, 15 USPQ2d 1321, 1329 (Fed. Cir. 1990). Since we credit Dr. Bach's declaration about the familiarity of the restriction-enzyme approach, we accord little weight to Factor 2 in this case.

[68] With regard to Factor 1, Scripps argues that a research program would have been necessary to produce a truncated hTF (Paper 63 at 15).

While Scripps' contention may have been literally true at the time of the invention, we regard it as little more than a rhetorical point. The mere fact that some experimentation is necessary is not dispositive if the experimentation is routine. *Ex parte Jackson*, 217 USPQ 804, 807 (Bd. Pat. App. 1982), cited with approval in *PPG Indus. Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996). As we noted above, the restriction-enzyme approach would have been routine at the time of the invention. Consequently, we accord no weight to Factor 1.

[69] With regard to Factors 6 and 7, Scripps argues that, while the level of skill in the art is high, the art is also unpredictable (Paper 63 at 15).

[70] Scripps provides us with no reason why the restriction-enzyme approach would have been

considered unpredictable.

However unpredictable the art may have been in general, the particular experiment in question--making a 1-219 residue hTF from a full-length hTF cDNA does not appear to have been unpredictable. Hence, we accept Scripps' concession of Factor 6, but accord little weight to Factor 7.

[71] With regard to Factor 5, Scripps argues that the prior art lacked any guidance regarding the proteins of the count (Paper 63 at 15-16).

Even allowing for hyperbole (since the art show considerable, but incomplete, understanding of hTF), the argument misses the point because it fails to take the teachings of the 166 application itself into account. With the teachings of the application, the production and use of 1-219 residue hTF appears to have required no more than routine experimentation. Consequently, we accord some, but not great, weight to Factor 5.

Considering all of the argued Wands factors together, the balance tips decidedly against ***1029** Scripps. One skilled in the art would have been able to make and use an embodiment within the scope of the count and described in the 166 application as of the filing date of the 166 application.

Additional findings on best mode

[72] Scripps argues that Nemerson failed to comply with the best-mode requirement of § 112(1) (Paper 63 at 18-19):

Inasmuch as Nemerson '166 fails to provide enablement, as well as written description, for any species within the purview of the Count, there can be no description of any best mode for preparing such species.

[3] [73] Scripps cites no precedent in which a best mode has been considered relevant to the question of constructive reduction to practice in an interference.

There are at least two fundamental errors in Scripps' argument. First, it presupposes that there is a best-mode requirement for a constructive reduction to practice. Second, it presumes that which Scripps must prove: that Nemerson had a best mode in mind at the time of filing.

[74] The first case that Scripps cites in its motion (Paper 63 at 9) is *Cromlish v. D.Y.*, 57 USPQ2d 1318 (BPAI 2000).

The first question is whether there is a best-mode requirement for a constructive reduction to practice. In *Cromlish*, the Board denied a motion attacking benefit on the basis of a best-mode violation. The Board explained that Cromlish had failed to provide any argument for why a best mode is required for a constructive reduction to practice. While the Board did not hold that there is no best-mode requirement for constructive reduction to practice, it provided reasons for skepticism about such an argument. [FN9] It is disappointing that Scripps could cite *Cromlish* and still make the very mistake that Cromlish made. Again, we need not resolve the question here because it is Scripps' responsibility to make out its own case in the first instance. Following *Cromlish*, we hold that Scripps' has not established a prima facie case for stripping Nemerson of its earliest constructive reduction to practice for failure to disclose a best mode.

The second question is whether Nemerson had a best mode that was not disclosed. *Northern Telecom, Ltd. v. Samsung Elec. Co.*, 215 F.3d 1281, 1286, 55 USPQ2d 1065, 1069 (Fed. Cir. 2000):

When the invention is defined, the best mode inquiry moves to determining whether a best mode of carrying out that invention was held by the inventor. If so, that best mode must be disclosed.

Scripps simply assumes that there was a best mode that was not described because, according to Scripps, no mode was described or enabled. This is the no-mode fallacy: enablement and best-mode are distinct requirements so a failure to enable does not automatically create a best-mode violation. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1330, 63 USPQ2d 1374, 1384 (Fed. Cir. 2002).

[75] Nemerson disclosed a mode of making the invention: site-specific mutagenesis [3017 at 14:5]

[76] Nemerson disclosed a mode of using: clotting assays in conjunction with Factor VII [3017 at 13:25-27 and 14:11-14].

The only evidence at all that Nemerson contemplated a different (and arguably better) mode came in Nemerson's opposition of all places when Dr. Bach described the restriction-enzyme approach in his declaration. Nemerson's opposition cannot be the source of Scripps' prima facie case.

[77] We find that Scripps has failed to establish that Nemerson had a best mode.

[78] We further find that Scripps has failed to establish that Nemerson improperly failed to disclose any known best mode.

Scripps preliminary motion 1 is DENIED.

Scripps preliminary motion 2: attacking the patentability of Nemerson's 262 application claims

[79] Scripps moves to have all of Nemerson's 262 claims corresponding to the count held to be unpatentable under 35 U.S.C. 112(2) as vague and indefinite and under § 112(1) as lacking enablement (Paper 64 at 2).

[80] Scripps also moves to have all of Nemerson's 262 claims corresponding to the count except parent claim 44 held to be unpatentable ***1030** under 35 U.S.C. 112(4) having improper dependency (Paper 64 at 2).

The threshold for indefiniteness is very high: the claim must be "insolubly ambiguous". *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375, 60 USPQ2d 1272, 1276 (Fed. Cir. 2001). If one of skill in the art would understand the scope of the claim when read in light of the specification, then the claim complies with § 112(2). Claims need not be models of clarity. As long as the meaning is discernible, then even if construction is difficult and the result equivocal, the claim is nevertheless definite. *Exxon Research & Eng'g Co.*, 265 F.3d at 1375, 60 USPQ2d at 1276; *All Dental Prodx LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80, 64 USPQ2d 1945, 1949 (Fed. Cir. 2002) (no indefiniteness despite the lack of clarity). The Court of Appeals for the Federal Circuit has made it very clear that an indefiniteness holding cannot be based on a putative lack of enabling disclosure. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 n.2, 52 USPQ 1029, 1034 n.2 (Fed. Cir. 1999) (explaining "definiteness and enablement are analytically distinct requirements"); *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692, 57 USPQ2d 1293, 1297 (Fed. Cir. 2001) (noting a claim may be definite, but not enabled).

Improper dependency can trigger a rejection under § 112. *In re Harnisch*, 631 F.2d 716, 716 n.1, 206 USPQ 300, 301 n.1 (CCPA 1980). The Office tends to treat such rejections as based on § 112(2), rather than § 112(4), *Ex parte Attig*, 7 USPQ2d 1092, 1093 (BPAI 1986), [FN10] but this distinction does not change the analysis. Again, the question is whether the claims are insolubly ambiguous.

[81] Nemerson 262 claims 37, 38, and 39 depend from Nemerson 262 claim 36 (Paper 64, Fact 4; admitted in Paper 60 at 3).

[82] Nemerson 262 claims 29 and 33 depend from Nemerson 262 claim 44 (Paper 64, Fact 2; admitted in Paper 60 at 3).

[83] Nemerson 262 claims 30 and 31 depend from Nemerson 262 claim 29 (Paper 64, Fact 2; admitted in Paper 60 at 3).

[84] Nemerson 262 claim 34 depends from Nemerson 262 claim 33 (Paper 64, Fact 2; admitted in Paper 60 at 3).

Claim 44

[85] Scripps argues (Paper 64 at 8-9) that claim 44 is indefinite because it is directed to a cloning vector, which will not necessarily express the recombinant protein as the claim requires.

[86] Claim 44 is (Paper 64, Fact 1; admitted in Paper 60 at 3):

Recombinant cloning vector which in a suitable host will express a nucleotide sequence coding for a fragment of human tissue factor including none or part of the transmembrane domain, wherein the fragment has activity in a coagulation assay.

A claim that is inoperative for a substantial measure of its scope may violate § 112(2). *In re Corkill*, 771 F.2d 1496, 1501, 226 USPQ 1005, 1009 (Fed. Cir. 1985). We begin our analysis by construing the contested limitations in the context of the language of the claims and of the underlying specification.

[87] Nemerson argues (Paper 60 at 12) that its 262 specification:

refers to "cloning vectors" to encompass vectors which can be used to replicate DNA as well as to express the DNA.

[88] Indeed, the 262 specification teaches [2011 at 11:29-12:2]:

The present invention provides for replicable recombinant vectors containing a cloned cDNA insert, the sequence of which codes for and, in a

suitable host, express the entire human tissue factor apoprotein or functional portions thereof.

[89] The 262 specification further teaches [2011 at 12:13-15]:

A preferred cloning vector is bacteriophage &lgr;gt11, an expression vector described by Young and Davis, Science 222:778-782, 1983.

[90] The 262 specification identifies [2011 at 12:6-9] plasmids as preferred cloning vectors.

[91] The 262 specification provides Example 8, entitled "Expression of Soluble Human Tissue Factor Protein" [2011 at 43:15-17].

***1031** [92] Example 8 illustrates the use of a plasmid, pLB5TF, that is a cloning vector, but not an expression vector [2011 at 44:9-15].

[93] Example 8 also illustrates the creation of an expression vector, pLB6TF, for soluble hTF by substituting an expression control sequence into pLB5TF [2011 at 44:16-45:5 and Fig. 11].

[94] Scripps counters that Nemerson's own expert testified that cloning vectors are distinct from expression vectors (Paper 71, Fact 1).

[4] Federal Circuit precedent counsels against the use of expert testimony to change the otherwise clear import of the specification. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584, 39 USPQ2d 1573, 1577 (Fed. Cir. 1996). In the context of the relevant art, Nemerson's choice of wording appears to be eccentric, but not indefinite. The specification would have given ample guidance to what Nemerson meant. Even within Nemerson's meaning there would be many cloning vectors incapable of expressing hTF as Example 8 showed, but the specification taught the difference between an expression vector and a non-expressing cloning vector. Scripps has not shown that the art is so unpredictable that non-expressing cloning vectors could not have been screened out using routine skill in the art. Moreover, Scripps' contention that claim 44 is vague because it is too broad confuses overbreadth with lack of enablement for the full scope of the claim. *In re Hyatt*, 708 F.2d 712, 714, 218 USPQ 195, 197 (Fed. Cir. 1983). On the other hand, while a claim must be enabled for its full scope, there is no requirement for an exhaustive disclosure of all possibilities. The test is whether the specification provides sufficient examples and guidance. *In re Vaeck*, 947 F.2d 488, 496 n.23 & text, 20 USPQ2d 1438, 1445 n.23 & text (Fed. Cir. 1991). As movant, Scripps bears the burden of showing by a preponderance of the evidence that the full scope is not enabled. While breadth of the claim is a *Wands* factor, Scripps has not shown why breadth is a problem for this limitation.

[95] Scripps argues that the "fragment of human tissue factor including none or part of the transmembrane domain" limitation is too broad (Paper 64 at 9).

[96] Scripps further argues (Paper 64 at 9-10) that the claim does not specify the DNA or the resulting protein with any precision.

[97] Scripps further argues (Paper 64 at 10) that the "activity" of claim 44 is ambiguous because it could be pro-coagulant or, and mutually exclusively, anti-coagulant.

Again, the question of over-breadth is not properly a question of indefiniteness as much as of enablement. Moreover, mathematical precision in claims is not required as long as one skilled in the art could have determined the scope. *Modine Mfg. Co. v. Int'l Trade Comm'n*, 75 F.3d 1545, 1557, 37 USPQ2d 1609, 1617 (Fed. Cir. 1996). One skilled in the art would know from the plain language of the claim that at least some of the transmembrane domain must be excluded and that the resulting protein must have activity in a coagulation assay. The fact that "activity" covers a broad range of possibilities makes the claim broad, not indefinite. As for enablement, again Scripps has not shown that it is more likely than not that the breadth of claim 44 would have created undue difficulty in the making or using of the claimed invention.

[98] Scripps urges that no "suitable host" is identified and that any living matter might be contemplated (Paper 64 at 10).

[99] Scripps again cites the declaration of Dr. Joyce [3025, ¶ ¶ 31-36] for the proposition that protein-expression host systems are not entirely predictable.

We have already discussed Dr. Joyce's testimony in this regard and have deemed it uncompelling. An analogy may help illustrate the problem with Scripps' use of his testimony. If a claim requires "fastening the plates together", there may be a wide range of choices for fastening (e.g., glue, welds, screws, nails,

rivets, etc.) that may be affected by the materials of the plates. Some combinations (e.g., welding and wooden plates) are not likely to work. The relevant question is not whether there is uncertainty or potentially impossible combinations, but rather whether the amount of selection and testing would be undue. Scripps has not pointed to any compelling evidence that suggests that an ordinary artisan after reading Nemerson's specification would have been daunted by the task of making or using the invention. We must presume skill, rather than its opposite, in the art. E.g., *In re Sovish*, 769 F.2d 738, 742-43, 226 USPQ 771, 774 (Fed. Cir. 1985) (an obviousness case).

[100] Scripps argues that the phrase "will express a nucleotide sequence coding for a fragment of human tissue factor" is "a mere functional limitation on the claimed vector" (Paper 64 at 11).

***1032** [101] Again, Dr. Joyce is cited (Paper 62 at 12) for the proposition that a wide range of DNA vectors might be used in the invention.

[102] The cited Joyce testimony provides background on protein expression [3025, ¶ ¶ 12-14 & 28].

Scripps is correct that a functional limitation does not necessarily correspond to any specific structure. Scripps has not, however, identified any per se rule that functional language is indefinite or not capable of enablement. Moreover, Dr. Joyce's testimony falls well short of providing a basis for concluding that one skilled in the art would consider the claims insolubly ambiguous or unduly challenging to put into practice.

Claim 29

[103] Claim 29/44 [FN11] (Paper 15 [FN12] at 4) further limits the hTF fragment of claim 44 to having a portion of the amino acid sequence of Formula I.

[104] Scripps argues that, under the doctrine of claim differentiation, either claim 44 must be further indefinite since it is not limited to Formula I or claim 29 fails the test of § 112(4) because it is not further limiting.

There is a strong presumption that claim 29 is narrower than claim 44 and thus it must be that claim 44 is open to implementations where the hTF fragment has a different amino acid sequence. *Transmatic Inc. v. Gulton Indus.*, 53 F.3d 1270, 1277, 35 USPQ2d 1035, 1041 (Fed. Cir. 1995); *Beachcombers v. Wilde Wood Creative Prods., Inc.*, 31 F32d 1154, 1162, 31 USPQ2d 1653, 1659 (Fed. Cir. 1994). What is missing is any reason why one skilled in the art would have any difficulty with this concept. One readily apparent explanation is that claim 44 is open to the inclusion of allelic variants of the hTF protein. Scripps has provided no basis for concluding that claim 44 is indefinite or not enabled in light of the scope imposed by claim 29.

Claim 30

[105] Claim 30/29/44 (Paper 15 at 4) further limits the hTF fragment to comprising the amino terminal of the extracellular hTF of Formula I.

[106] Claim 31/29/44 (Paper 15 at 4) further limits the hTF fragment to comprising the amino terminal residues 1-219/220 of Formula I.

[107] Scripps argues (Paper 64 at 13) that the claimed fragments have no inherent activity.

We previously found the inherent-activity argument to be unpersuasive.

[108] Scripps also argues (Paper 64 at 13) that the "219/220" limitation is necessarily indefinite.

[109] Nemerson points (Paper 60 at 16) to its specification, which teaches [2011 at 9:28-10:4 and 21:12-15] that the soluble extracellular portion of hTF is "approximately 1-219/220".

[110] Nemerson also points (Paper 60 at 17) to Dr. Bach's testimony [2087, ¶ 5] that one skilled in the art would have appreciated that the dividing line between the extracellular moiety and the transmembrane moiety is somewhat arbitrary and so "219/220" would be understood to embrace either alternative.

[111] We find Dr. Bach's testimony on "219/220" to be credible.

There is nothing insolubly ambiguous about claim 31 presenting two alternatives in the form of "219/220".

Claims 33 and 34

[112] Claim 33/44 further limits the hTF fragment encoded to N-terminal amino acid residues 1-242 (Paper 15 at 4).

[113] Claim 34/33/44 requires the hTF fragment encoded to comprise N-terminal amino acid residues

1-227 (Paper 15 at 4).

[114] Scripps' only argument with regard to claims 33 and 34 is that the added limitations do not cure other defects of Nemerson's claims.

Since we have not yet found such defects, Scripps' argument for claims 33 and 34 fails to persuade.

Claim 36

[115] Nemerson 262 claim 36, the other independent claim in the 262 application, provides (Paper 15 at 4-5, double underlining [italics] added):

A host organism which produces a fragment of human tissue factor having activity in a coagulation assay, the host being transformed by a recombinant cloning vector containing a DNA insert which codes for a fragment of human tissue factor selected from the group consisting of human tissue factor including none or part of the transmembrane domain, soluble human tissue ***1033** factor consisting of the N-terminal amino acids 1-219/220 of human tissue factor as provided in *Figure* I, truncated human tissue factor consisting of the N-terminal amino acids 1-227 of human tissue factor as provided in *Figure* I, and truncated human tissue factor consisting of the N-terminal amino acids 1-242 of human tissue factor as provided in *Figure* I.

[116] Scripps argues (Paper 64 at 13) that the "219/220" limitation is ambiguous.

We have already held that this limitation would not be insolubly ambiguous to one skilled in the art reading the claim in light of the specification.

[117] Scripps further argues (Paper 64 at 13-14) that the "Figure I" limitation is indefinite because no such figure exists in the 262 application.

[118] Nemerson notes (Paper 60 at 19) that claim 38 and claim 39, both of which depend from claim 36, properly refer to "Formula I".

[119] Nemerson contends that the meaning of "Figure I" would have been apparent to one skilled in the art reading claim 36 in the context of the specification and other claims.

[120] Nemerson did not file a motion to amend claim 36 to change "Figure I" to "Formula I".

A lax standard for indefiniteness is well suited to validity contests in courts where there is no opportunity to amend away even trivial defects in the claims. By contrast, this sort of rejection rarely arises in proceedings within the Office because applicants usually rush to correct the defect as soon as it is pointed out. Nemerson did not do so here. We are thus confronted with the dilemma of holding a claim unpatentable for a seemingly trivial reason or of rewarding a failure to correct a plain, acknowledged mistake. Unlike district courts, the Office is not required to construe a claim to the extent possible so as to preserve its patentability. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1028 (Fed. Cir. 1997). An applicant's liberty in defining the claimed subject matter is bounded, in part, by the requirement to provide clear notice to the public of what the applicants regard as their invention. One mechanism for enforcing the requirement is rejection under § 112(2).

[5] In an ex parte proceeding, an examiner may enter an amendment to fix obvious mistakes. 37 C.F.R. § 1.121(g). Whether we should exercise analogous discretion in an inter partes proceeding where a movant has clearly identified the problem and the applicant has made no effort--even contingently--to protect its interests is more problematic. In determining whether we should exercise our discretion to permit correction of the mistake in this case, we draw an analogy to the three categories of mistakes that the Federal Circuit identified for corrections under 35 U.S.C. 255: (1) those that are immediately apparent and leave no doubt as to what the mistake is; (2) those where the mistake is not immediately apparent because it makes sense in context; and (3) those where the fact of a mistake is immediately apparent, but it is not clear what the mistake is. *Superior Fireplace Co. v. Majestic Prods.*, 270 F.3d 1358, 1370, 60 USPQ2d 1668, 1677 (Fed. Cir. 2001) (involving a type 3 mistake). The mistake here is a type 2 mistake because a reference to "Figure I" makes sense in the context of the claim. The Federal Circuit has further explained that even in the absence of an attempt to correct, a claim may be construed as if corrected, but only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims. *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1354, 69 USPQ2d 1128, 1132 (Fed. Cir. 2003) (not permitting correction). Read in the context of the specification and other claims, the need to correct "Figure" to "Formula" is readily apparent.

Nemerson's failure to move to correct a plain, acknowledged error in this case is inexplicable. Nevertheless, we will exercise our discretion to DEFER decision on claim 36 (and by extension its dependent claims 37-39) to permit Nemerson one last chance to correct the mistake. Nemerson has *30 days from the entry of this decision* to file an amendment changing each instance of "Figure I" in claim 36 to "Formula I", and making no other alteration to any of the claims. Failure to file such an amendment will result in the automatic GRANTING of Scripps' motion with regard to claims 36-39.

Enablement

[121] Scripps argues (Paper 64 at 15) that "[o]ne of ordinary skill in the art cannot practice the full scope of the invention if the scope is indeterminate".

As we have discussed above, it is error to confuse over-breadth and indefiniteness. In any case, we have generally rejected Scripps' indefiniteness arguments. A lack of enablement ***1034** for the full scope of a claim, however, is a legitimate rejection. *In re Cortright*, 165 F.3d 1353, 1356, 49 USPQ2d 1464, 1466 (Fed. Cir. 1999). As discussed previously, the key question is one of undue experimentation, *Wands*, 858 F.2d at 737, 8 USPQ2d at 1404, but the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; as long as the amount of experimentation is not unduly extensive. *PPG Indus. Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996). We start with the presumption that the disclosure is enabling. *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995).

[122] Scripps relies on the testimony of Drs. Joyce [3025], Nemerson [3016], and Konigsberg [3014] for the proposition that there was much uncertainty in the art in 1987.

[123] The filing date for the 262 application is 7 June 1995 (Paper 1 at 3).

[6] We have already considered the testimony of Drs. Joyce, Nemerson, and Konigsberg on the question of the state of the art in 1987. We concluded that the testimony did not support a generalized attack on the enablement. More to the point, the state of art in 1987 is not the relevant question. The filing date of the application, in this case June 1995, is the relevant time for the determining enablement. *Brana*, 51 F.3d at 1566 n.19, 34 USPQ2d at 1441 n.19. In the absence of intervening prior art, whether a parent application adequately complies with § 112(1) is not determinative of the patentability of claims in a child application. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1918 (Fed. Cir. 2000).

[124] Scripps also argues that the working examples use expression vectors rather than the claimed cloning vectors.

We dealt above with the cloning vector versus expression vector distinction and concluded that it did not amount to much uncertainty. Nemerson's eccentric choice of terminology if anything narrows the practical scope of the claims because, as explained above, the vector must be capable of expression, but it must also by the terms of the claim be capable of cloning. Nemerson's 262 specification offers ample guidance to one skilled in the art to determine whether a vector can clone and express an hTF gene.

[125] Scripps also restates the "host" uncertainty argument with regard to claim 36.

As previously explained, identification of suitable host organisms would have been within the ordinary skill in the art.

Improper dependent claims

[126] Scripps argues (Paper 64 at 19-20) that the following claim limitations show improper dependency:

44 a fragment of human tissue factor including none or part of the transmembrane domain

29/44 a fragment of human tissue factor having a portion of the amino acid sequence shown in Formula I

30/29/44 a fragment of human tissue factor comprising the amino extracellular domain. . .provided in Formula I

31/29/44 a fragment of human tissue factor comprising the N-terminal acids 1- 219/220. . .provided in Formula I

[7] Scripps' argument with regard to claim 29 is based on the faulty premise that "having" is necessarily open-ended. The use of "having" does not create a presumption of openness: rather the

claims must be considered in context to determine the effect of "having" on claim scope. *Crystal Semiconductor Corp. v. TriTech Microelec. Int'l, Inc.*, 246 F.3d 1336, 1348, 57 USPQ2d 1953, 1959 (Fed. Cir. 2001), distinguishing the open construction used in *Regents of the Univ. of Cal. v. Eli Lilly &Co.*, 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997). Read in context, i.e., with due consideration to the express incorporation of the limitations of claim 44, claim 29 further limits the hTF fragment of claim 44 to the relevant portions of Formula I. The construction Scripps' proposes, that claim 29 opens up the scope of claim 44 to include additional embodiments, flies in the face of the plain language of the claim. Claims 30 and 31 further limit the hTF fragment to two embodiments (1-219 and 1-220) that Nemerson has provided as alternative definitions of the extracellular domain. Since both expressly require the amino [N-] terminal to be included, they further limit both claims 44 and 29, which are open to fragments lacking portions of the amino terminal.

[127] Scripps argues (Paper 64 at 20) that claim 33/44 is improper because it is open to encoding through residue 242, apparently all ***1035** of the transmembrane domain, while claim 44 "includes none or part of" the transmembrane domain.

[128] Nemerson does not argue that "part of" can mean "all of".

[129] Instead, Nemerson notes (Paper 60 at 25-26) that the 262 specification defines the transmembrane domain as "comprising approximately amino acids 220 to 242".

[130] Nemerson further cites Dr. Bach's testimony for the proposition that one of skill would have understood that amino acid 243 might also be included in the transmembrane domain.

Nemerson's attempt to make a virtue out of its own imprecision fails. Nemerson's construction of "transmembrane domain" to be broader than amino acid residues 220-242 requires the reader to have greater certainty about the limits of the hTF transmembrane domain than Nemerson appeared to have in the 262 specification or even now in its brief. Latitude in claim drafting is not license for drafting sloppiness. Ultimately, the drafter must be held accountable for the scope of the claims. *Morris*, 127 F.3d at 1056, 44 USPQ2d at 1029. Claim 33 is not patentable under § 112(2).

[131] Scripps notes (Paper 64 at 20) that claim 34/33/44, in which the hTF comprises residues 1-227, is broader than parent claim 33/44, in which the hTF is limited to residues 1-242.

[8] Claim 33 is limited to a single end point for the encoded hTF fragment, residue 242, while claim 34 provides an end-point range starting as low as residue 227 and extending to at least residue 242.

[132] Nemerson acknowledges the problem as a typographical error, explaining that claim 34 should depend directly from claim 44, rather than through claim 33 (Paper 60 at 26).

[133] Despite this acknowledgment, Nemerson did not move to correct the defect.

Again, Nemerson must be held to account for its sloppy claim drafting and its failure to cure plain defects in the claims. Unlike in a district court proceeding, in an interference a party may amend its claims. [FN13] The time to do so is in response to the motion that brings the defect to light. [FN14] Moreover, parties are permitted to file contingent motions--thus allowing a party to challenge the merits of the putative defect, but also offer a cure in the event the defect exists. Nemerson was provided with an opportunity to amend its claims during Time Period 2 by filing a motion under 37 C.F.R. § 1.633(i) (2003). Nemerson may not shift the burden of deciphering its typographical errors to its opponent, the Board, and the public. In this case, which of the many possible cures is the right one cannot be discerned from context. [FN15] Consequently, this is a *Superior Fireplace Co.* type 3 error that is not amenable to simple correction. The ambiguity between claims 33 and 34 is precisely the sort of problem that § § 112(2)/112(4) exist to prevent.

[134] Scripps finally (Paper 64 at 20-21) argues that claims 37-39 improperly broaden claim 36.

[135] Claim 36 defines (Paper 15 at 4-5, bracketed numbering and indenting added) the relevant hTF fragment as:

selected from the group 1OE consisting of

human tissue factor 2OE including none or part of the transmembrane domain,

soluble human tissue factor 3OE consisting of the N-terminal amino acids 1- 219/220 of human tissue

factor as provided in Figure I,

truncated human tissue factor 4OE consisting of the N-terminal amino acids 1- 227 of human tissue factor as provided in Figure I,

and truncated human tissue factor 5OE consisting of the N-terminal amino acids 1-242 of human tissue factor as provided in Figure I.

Claim 36 offers a Markush group of alternatives for the hTF fragment. A Markush group is by its nature "closed", i.e., it is not open to the inclusion of unlisted group members. In this regard 1OE "consisting of" is not only consistent with Markush practice, it is required to close the group. ***1036***Abbott Labs. v. Baxter Pharma. Prods.*, 334 F.3d 1274, 1280-81, 67 USPQ2d 1191, 1196-97 (Fed. Cir. 2003). "Consisting of" always signals a closed construction. *AFG Indus., Inc. v. Cardinal IG Co.*, 239 F.3d 1239, 1245, 57 USPQ2d 1776, 1780 (Fed. Cir. 2001). The use 3OE-5OE of "consisting of" in the last three Markush alternatives calls in each case for a closed construction.

By contrast, "comprises" consistently signals an open construction. *Id.*, 239 F.3d at 1245, 57 USPQ2d at 1780. "Includes" is as open as "comprises". *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1345, 65 USPQ2d 1385, 1408 (Fed. Cir. 2003). It is well-established, however, that even open transitions can be limited by the context in which they occur. *In re Crish*, 393 F.3d 1253, 1257, 73 USPQ2d 1364, 1367 (Fed. Cir. 2004) (affirming a construction in which the opening effect of an earlier occurrence of "comprising" outweighed the closing effect of a subsequent occurrence of " consists"). The 2OE "including" transition opens up the first hTF fragment alternative, but it is used in conjunction with "none or part of", which has the effect of defining the fragment in terms of what is being excluded rather than what is being included. Thus, the first Markush alternative is open to the inclusion of other elements as long as some or all of the transmembrane domain is excluded.

[136] Claims 37-39 all depend from claim 36 and limit the hTF fragment as follows (Paper 15 at 5):

37/36 comprises the extracellular domain of mature human tissue factor apo-protein.

38/36 comprises the N-terminal amino acids 1-219/220 of mature human tissue factor as provided in Formula I.

39/36 comprises the N-terminal amino acids 1-227 of mature human tissue factor as provided in Formula I.

[9] Scripps' argument--that "comprises" in the dependent claims opens up these claims--depends on reading the transition in isolation. Under § 112(4), we must construe each dependent claim to incorporate all of the limitations of claim 36. As in *Crish*, lexical order matters. In claim 36, the language of exclusion in the first Markush alternative and the use of "consisting of" for the other three Markush alternatives create the relatively closed context in which claims 37-39 must be construed. The dependent claims do not have to be, and thus in context cannot reasonably be, read to include matter already excluded in claim 36. Our reading of the claims does not render "comprises" a nullity since the first Markush alternative, which uses "including" is not very closed. It is open to a construction that includes N-terminal fragments with part or, but not all of, transmembrane domain. Since the transmembrane domain appears to include residues 220-242, claims starting with none of the transmembrane domain (claims 37 and 38) or starting seven or eight residues into the transmembrane domain (claim 39) leave some room for additional embodiments.

For the reasons given above, Scripps preliminary motion 2 is GRANTED with respect to claims 33 and 34, DEFERRED with respect to claims 36-39, and otherwise DENIED.

Scripps preliminary motion 3: attacking the patentability of Nemerson's 581 application claims

[137] Scripps moves to have all of Nemerson's 581 claims corresponding to the count held to be unpatentable under 35 U.S.C. 112(1) as lacking adequate written description and enablement (Paper 65 at 2).

[138] Nemerson 581 claims 15, 42, 43, 45, and 46 are independent (Paper 15 at 3).

[139] Claim 15, which is typical of the independent claims in structure, reads (Paper 15 at 3):

A soluble human tissue factor expressed from a polynucleotide molecule encoding an amino acid sequence from amino acid residue one to amino acid residue 209 as provided in Figure 17.

[140] Scripps begins by construing the claims to be product-by-process claims because they define the resulting hTF product in terms of how it is made rather than limiting it to the disclosed sequence (Paper 65 at 10-12).

[141] According to Scripps, the claims thus encompass proteins that are in no way directly limited to the recited sequences (Paper 65 at 10-12).

If Scripps were correct about the ill-defined scope of Nemerson's 581 claims, it would follow that Nemerson's 581 specification does not support the full scope of such ill-defined proteins.

[142] Scripps does not argue that the claims are indefinite.

Scripps has a point that the independent claims are very oddly worded. For instance, while claim 15 is directed to a soluble hTF protein, it does not claim "A soluble human tissue factor comprising amino acid residues ***1037** 1- 209 of Figure 17". Instead, the soluble hTF is defined in terms of being expressed from a polynucleotide that can encode residues 1-209. Thus, the product is indirectly defined in terms of residues 1-209, but at first blush does not appear to be directly limited to having residues 1-209.

The most reasonable solution to this apparent ambiguity is that claim 15 is not open in any sense. The tissue factor must be expressed from the polynucleotide. The polynucleotide must encode residues 1-209. Nothing in the language of the claim preserves the possibility that the polynucleotide encodes other proteins as Scripps suggests. See *Lampi Corp. v. American Power Prods., Inc.*, 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) (requiring an openness determination to take the teachings of the specification into account).

The Board is, of course, obligated to construe claims broadly as it reasonably can, but the reasonable limits of that breadth are set by the plain language of the claims and the teachings of the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). There is a certain circularity in Scripps' argument: by untethering the claims from the specification, Scripps can give the claims a construction that cannot be supported by the specification. Yet the case law makes clear that a claim must not be casually construed to be so broad as to violate § 112(1). E.g., *Digital Biometrics v. Identix*, 149 F.3d 1335, 1344, 47 USPQ2d 1418, 1424 (Fed. Cir. 1998) (explaining that when a claim that is susceptible to a broad, unsupported meaning and a narrower, supported meaning, the narrower construction should be chosen). [FN16] Since the structure of the independent claims other than claim 46 lack open-ended transitions and neither party has pointed to a basis in the specification for reading these claims broadly, we decline to read them as encompassing anything more than the plain language of the claims requires.

Written description of claims 15 and 47

[143] Scripps argues that there is no support for a 1-209 residue embodiment (Paper 65 at 12).

[144] Nemerson responds (Paper 61 at 11-12) that the 581 specification offers support for a 1-209 residue embodiment created by cyanogen bromide [CNBr] cleavage [3022 at 24:13-19]:

A partial amino acid sequence, spanning residues 211-244, of the carboxy-terminal CNBr peptide (residues 211-263), was obtained by succinylating the intact protein and cleaving at the single methionine residue in the protein, Met210, with CNBr, followed by gas-phase sequence analysis. The carboxy-terminal CNBr peptide was prepared from about 60 <<mu>>g of the placental apo-protein.

[145] The cited portion of the 581 specification is directed to the production of a 211-244 residue fragment rather than a 1-209 residue fragment.

[10] [146] The cited portion of the 581 specification does not expressly describe the creation of a 1-209 residue fragment.

[147] At best, the cited portion of the 581 specification suggests the creation of an N-terminal fragment terminating at approximately residue 210.

[148] Nemerson also argues (Paper 61 at 13) that a polynucleotide encoding a 1-209 residue fragment is shown in Figure 17.

[149] Figure 17 shows the entire hTF gene encoding the entire hTF protein, including its signal sequence.

[150] Nemerson explains (Paper 61 at 13) that one skilled in the art would have been able to use computers and restriction enzymes to cleave the polynucleotide at "appropriate" sites.

[151] Scripps notes (Paper 72 at 6) that CNBr

cleavage of an extant protein is not what is claimed and in fact differs from the claimed expression product of a polynucleotide encoding residues 1-209.

[152] Nemerson's reliance on the CNBr example implies, but does not actually show, that CNBr cleavage at Met210 would necessarily produce a 1-209 residue hTF fragment.

[153] Indeed, as Scripps notes (Paper 72 at 6, citing Nemerson's expert Dr. Bach [3040]), CNBr actually would produce cleavage between residues 210 and 211. [FN17]

***1038** To fulfill the written description requirement, a patent specification must describe the claimed invention in detail sufficient for one skilled in the art to conclude that the inventor invented the claimed invention. A description that renders the claimed invention obvious is not sufficient. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566-67, 43 USPQ2d 1398, 1404-05 (Fed. Cir. 1997); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Moreover, if the disclosure is said to be inherent, the missing descriptive matter must necessarily be present in the specification such that one skilled in the art would recognize such a disclosure. *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159, 47 USPQ2d 1829, 1834 (Fed. Cir. 1998).

[154] In view of the portions of the 581 specification cited to us, Scripps is correct that the 581 specification does not describe an hTF fragment expressed from a polynucleotide encoding residues 1-209.

[155] Claim 47 depends from claim 15 and thus also lacks adequate written description.

Written description of claim 42

[156] Nemerson 581 claim 42 is (Paper 15 at 3):

A soluble human tissue factor expressed from a polynucleotide molecule encoding an amino acid sequence from amino acid residues [sic] one to amino acid residue 219 as provided in Figure 17.

[157] Scripps argues (Paper 65 at 13) that Nemerson's 581 disclosure identifies a fragment that terminates at "approximately amino acids 219/220".

[158] Scripps further argues (Paper 65 at 14) that Nemerson's 581 disclosure identifies the soluble fragment as "compris[ing] the extracellular domain", which Scripps notes is open-ended.

[159] Scripps contends these descriptions are too ambiguous to support the polypeptide of claim 42.

[160] Scripps did not allege § 112(2) indefiniteness as a basis for the unpatentability of claim 42.

[11] [161] The fact that the 581 specification can be read as open to embodiments other than the specifically recited embodiments, does not detract from the specific disclosure of those embodiments.

[162] One skilled in the art would have understood Nemerson to have disclosed at least the embodiments with explicitly recited end-points.

[163] As discussed above, one skilled in the art would have understood "approximately amino acids 219/220" as explicitly identifying at least the embodiments 1-219 and 1-220.

[164] Nemerson relies (Paper 61 at 10) on its teaching in the last paragraph of the Summary of the Invention [3022 at 9:25-10:4]:

Of particular importance, such vectors have also allowed for production of a soluble form of the tissue factor protein which is missing the carboxy-terminal hydrophobic membrane spanning-portion of the protein. In particular, the vectors provide for expression of a soluble active tissue factor comprising the extracellular domain or the approximately N-terminal 219/220 amino acids of the mature human tissue factor apoprotein and a truncated human tissue factor comprising the 1-227 amino acids of the mature human tissue factor apoprotein. Such soluble human tissue factor and truncated human tissue factor proteins and functional portions thereof, i.e., peptides derived from the extracellular domain of human tissue factor are especially useful as diagnostic reagents and anticoagulant agents.

[165] We find sufficient written description for claim 42.

Written description of claim 43

[166] Nemerson 581 claim 43 is (Paper 15 at 3):

A truncated human tissue factor expressed from a polynucleotide molecule encoding an amino acid sequence from amino acid residues [sic] one to amino acid residue 227 as provided in Figure 17.

[167] Scripps repeats the "encompassing" argument also made in regard to claim 15. We consider the argument no more persuasive for claim 43 than it was for claim 15.

[168] Scripps argues (Paper 65 at 14) that the 581 specification discloses the expression of a truncated hTF "encompassing amino acids 1-227", but that it is not clear from the specification what was actually made.

Written description does not require an actual reduction to practice. Instead, what is required is description *in the specification* sufficient ***1039** to notify one skilled in the art that the inventor had invented the claimed invention. 35 U.S.C. 112(1); *Regents of the Univ. of Cal.*, 119 F.3d at 1566, 43 USPQ2d at 1404.

[169] Scripps further notes (Paper 65 at 14) that "truncated" hTF is described as lacking the last 37 residues, which would result in a 1-226 residue fragment.

[170] Scripps further argues (Paper 65 at 14-15) that Nemerson appears to use "soluble" and "truncated" interchangeably [citing 3022 at 43:6-18].

[171] The portion Scripps cites (p. 43:6-18) refers to Example 8, which teaches the 1-219/220 residue embodiment.

[172] The 1-219 and 1-220 residue embodiments are indisputably truncated in relation to the full-length hTF.

[173] The 1-227 residue embodiment is likewise truncated.

[174] A key premise of the 581 specification is that the 1-219/220 residue embodiments are the extracellular domain of hTF and thus soluble.

[175] Neither party has pointed to a teaching in the 581 specification regarding the solubility of the 1-227 residue embodiment.

[176] Indeed, the portion of the specification on which Nemerson relies [3022 at 9:25-10:4] appears to distinguish between soluble 1-219/220 residue fragments and "truncated" 1-227 residue fragments.

[177] Again, Scripps did not allege § 112(2) indefiniteness as a basis for the unpatentability of claim 43.

[178] Nemerson again relies (Paper 61 at 10) on its teaching in the last paragraph of the Summary of the Invention [3022 at 9:25-10:4].

[12] [179] Scripps has not pointed to an express or constructive disavowal of the 1-227 residue embodiment in the 581 specification.

While we could wish that the 581 specification were more consistent in its terminology and counting, we have no serious doubt that the 581 embodiment expressly teaches an expressed 1-227 residue embodiment. Even if some of the rest of the specification can be read to be inconsistent with the 1-227 residue embodiment (because of inconsistent use of "truncated" or because arithmetic produces a 1-226 residue embodiment), there is no "teaching away" concept for written description short of an express disavowal of the subject matter. Compare *Micro Chem. Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1260, 52 USPQ2d 1258, 1265 (Fed. Cir. 1999) (embodiment with disadvantages not automatically excluded from scope of invention) with *Signtech v. Vutek*, 174 F.3d 1352, 1357, 50 USPQ2d 1372, 1375 (Fed. Cir. 1999) (embodiment disclosed as incapable of performing claimed function must be excluded from scope of invention) (both for purposes of corresponding structure under § 112(6)); see also *Celeritas Tech. Ltd. v. Rockwell Intl. Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998) (holding "teaching away" to be inapplicable in the analogous context of anticipation).

[180] The 581 specification adequately describes the subject matter of claim 43.

Written description of claim 45

[181] Nemerson 581 claim 45 is (Paper 15 at 3):

A human tissue factor protein expressed from a polynucleotide molecule encoding an amino acid [sic, sequence?] as provided in Figure 17, wherein the molecule does not encode amino acid residues 220 to 242.

[182] Scripps repeats the "encompassing" argument also made in regard to claim 15.

We consider the argument no more persuasive for claim 45 than it was for claim 15. We decline to read claim 45 as broader than its plain language. The plain language of the claim, however, poses a problem for Nemerson. The claim requires an hTF protein produced by expression of the amino acid sequence

shown in Figure 17 minus the nucleotides encoding residues 220-242. Claim 45 thus would include at least the hTF protein with both residues 1-219 and residues 243-263, but not residues 220-242.

[13] [183] Nemerson discloses that residues 220-242 define the transmembrane domain [3022 at 15:23-16:8].

[184] Nemerson does not point us to any disclosure of a transmembrane domain-free, but otherwise complete, hTF protein in the 581 specification.

[185] We can find no written description of the 1-219/243-263 residue protein in the 581 specification.

[186] Indeed, all of the embodiments that eliminate some or all of the transmembrane domain appear to also eliminate the cytoplasmic domain (residues 243-263) [e.g., 3022 at 20:19-21].

[187] Nemerson points (Paper 61 at 12) to the disclosure of Figure 17 and the disclosure of the sequence of the transmembrane domain, and argues:

***1040** One skilled in the art would thus have, within the specification of Nemerson '581, a detailed description of exactly what is claimed, as well as how to make and use it.

We do not find Nemerson's argument to be persuasive. Nemerson does not explain how one skilled in the art would appreciate that the 1-219/243-263 residue protein is disclosed explicitly or implicitly, but instead offers an enablement sort of response. Assuming for the moment that one skilled in the art could make and use the 1-219/243-263 residue protein, Nemerson appears to rely on precisely the sort of analysis that was rejected in *Eli Lilly & Co.*, 119 F.3d at 1566-67, 43 USPQ2d at 1404-05, and in *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

[188] In view of the portions of the 581 specification cited to us, Scripps is ultimately correct that the 581 specification does not describe an hTF protein expressed from a polynucleotide encoding residues 1-219 and 243-263, but not 220-242.

Written description of claims 46 and 48

[189] Nemerson 581 claim 46 is (Paper 15 at 3):

A human tissue factor protein expressed in a recombinant non-human host from a polynucleotide molecule encoding an amino acid sequence comprising amino acid residues one and [sic, to?] 219 as provided in Figure 17.

[190] Scripps argues (Paper 65 at 15) that the "comprising" transition expands the scope of claim 46 such that it could include the "entire full length tissue factor protein". [FN18]

[191] Scripps further argues (Paper 65 at 15) that the claim is open to the use of any recombinant non-human host, which Scripps characterizes as "cells from all categories of non-human living matter, including eukaryotes and prokaryotes."

[192] As discussed above, Nemerson has identified both the full length hTF protein and a variety of intermediate hTF protein fragments that include residues 1-219.

[193] Nemerson also discloses [e.g., 3022 at 9:11-24] a variety of recombinant non-human host cells suitable for the invention, including both prokaryotes and eukaryotes.

[194] Again, Scripps did not allege § 112(2) indefiniteness as a basis for the unpatentability of claim 45.

[195] Claim 48 further limits (Paper 15 at 3) the host limitation of claim 46 to "bacterial hosts".

[14] While we agree with Scripps that the "comprising" transition opens the scope of claim 46, it does so with respect to the phrase "amino acid residues one to 219 as provided in Figure 17." Thus, the claim is open-ended with respect to the amino acids that may be included in addition to residues 1- 219 of Figure 17. [FN19] Scripps' argument that the claim would include the full-length hTF protein, a protein explicitly disclosed in the 581 specification, does not support a finding that the claim lacks adequate written description. Nemerson explains uses for both the full-length and soluble embodiments. Similarly, while the range of possible hosts is very broad, the specification discloses hosts broadly. Consequently, we cannot find an adequate basis in Scripps' argument to hold the claim to lack adequate written description.

Enablement findings

[196] Scripps bases much of its enablement argument against the 581 claims on its broad construction of the claims (Paper 65 at 17-18).

We rejected Scripps' broad claim constructions above in the context of Scripps' written description arguments.

[197] Scripps argues (Paper 65 at 18) that the use of the term "soluble" in claims 15, 42 and 47 is ambiguous.

[198] Scripps has not argued that these claims are indefinite.

It is just as well since, despite Scripps' attorney argument, we doubt one skilled in the art would find "soluble" to be "insolubly ambiguous". *Exxon Research*, 265 F.3d at 1375, 60 USPQ2d at 1276.

***1041** [199] Scripps has not presented any evidence that the specific polypeptides claimed (claim 15, residues 1-209; claim 47, residues 1-209, not glycosylated; and claim 42, residues 1-219) are not soluble or that one skilled in the art would need undue experimentation to make them soluble.

> [15] Again, we start with the presumption that the disclosure is enabling. *Brana*, 51 F.3d at 1566, 34 USPQ2d at 1441. Scripps' attorney argument is no substitute for evidence. *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595, 44 USPQ2d 1609, 1615 (Fed. Cir. 1997). A major premise of the 581 application is that the polypeptides consisting essentially of residues 1-209 and 1-219 are inherently soluble. We do not consider the 581 application for the truth of these assertions. Paper 2, Standing Order, at ¶ 14.6; accord Fed. R. Evid. 801(c) & 802. Rather, we note that Scripps as movant bears the burden of proof. Consequently, we need not be convinced by the 581 application in order to reject Scripps' unsupported argument. *KP Permanent Make-Up, Inc. v. Lasting Impression I, Inc.*, 543 U.S. 111, 72 USPQ2d 1833, 1837 (2004).

[200] Scripps argues (Paper 65 at 19) that "truncated" is similarly vague in claim 43, pointing to the 37-residue deletion language [3022 at 48:5-10] among other things.

[201] In the 581 disclosure, "truncated" is used in a manner consistent with its well-known meaning. [FN20]

[202] Claim 43 is limited to the first 227 amino acid residues out of the 263 residues in naturally occurring hTF.

[203] Again, Scripps does not argue the claim is indefinite.

In view of our claim construction for claim 43, Scripps' argument is not tenable. Claim 43 is limited to the 227 residue N-terminal fragment, which is plainly truncated. It is not apparent from Scripps what if any undue experimentation would be necessary to make and use the claimed invention.

[204] With regard to claim 45, Scripps argues (Paper 65 at 19) that the claim is broad enough to include the leader sequence and cytoplasmic domain.

[205] In the 581 disclosure, the leader sequence (also called the signal peptide) is the 32-residue N-terminal sequence appearing before residue 1 of Figure 17, which is removed during cellular processing of the preprotein into its mature form [3022 at 15:23-16:8].

[206] Scripps does not explain how the presence of the signal peptide or the cytoplasmic domain would render the claim unenabled.

We have already found claim 45 to lack written description in the 581 specification. It is difficult to imagine why one skilled in the art would want to make such an unusual polypeptide when the simpler 1-219 residue hTF would be so much easier to make. Nevertheless, Scripps has not shown why this odd protein would require undue experimentation to make or use. The *Brana* presumption of enablement is contingent on an adequate written description, but we decline to convert a written description problem into an enablement problem.

[207] Scripps argues (Paper 65 at 19-21) that claims 46 and 48 lack enablement for their full scopes because the phrase "recombinant non-human host" is not enabled for its full scope.

[208] Scripps notes that there are "innumerable" non-human hosts available(Paper 65 at 21).

While we agree that there are huge numbers of non-human hosts, and even suspect that at least some of them would not be suitable for one reason or another, the fact that it would be tedious to identify all of the possible hosts does not make the invention impossible to make or use without undue diligence. Indeed, Scripps does not argue that the screening process for any particular host cell would be anything other than routine. Tedium is not the test for undue experimentation. *PPG Indus. Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623

(Fed. Cir. 1996). The case law clearly permits the inclusion of some inoperative embodiments as long as the number is not significant. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984). Scripps had the burden of proving by a preponderance of evidence that the "significant number" threshold had been passed. It did not do so. Again, attorney argument is no substitute for facts.

For the reasons stated above, Scripps preliminary motion 3 is GRANTED with respect to claims 15, 45, and 47, but is otherwise DENIED.

***1042** Nemerson preliminary motion 5: attacking the patentability of Scripps '931 patent claims for lack of enablement

[209] Nemerson argues (Paper 40 at 2) that Scripps' 931 patent claims lacked enabling description as of the filing date of the underlying 079 specification and as of the filing date of the 939 and 103 applications to which Scripps has been accorded benefit.

Since Nemerson is moving for judgment of unpatentability of Scripps' involved claims, the sufficiency (or not) of the enabling disclosure in the benefit applications is moot. See *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1918 (Fed. Cir. 2000) (§ 120 benefit does not matter for a determination under § 112(1)). Nemerson has not argued that the claims are unpatentable on the basis of intervening prior art.

[210] Scripps has two 931 patent claims (Paper 7, attachment):

1. A composition comprising an acqueous [sic, aqueous] solution of human tissue factor heavy chain protein wherein said protein is soluble and has an amino acid residue sequence represented by FIG. 1 from position 1 to position 219.

2. The composition of claim 1 wherein said human tissue factor heavy chain protein is dispersed in a phospholipid.

[211] Nemerson does not provide separate arguments for claims 1 and 2.

Claim 1 is open-ended with regard to the nature of the composition, requiring only that it be aqueous and that it include the recited protein. The recited protein itself includes at a minimum residues 1-219 of Figure 1, but must also be soluble. The solubility requirement excludes full-length hTF from inclusion in the scope of claim 1.

[212] Nemerson contends (Paper 40 at 9, emphasis in original), citing the testimony of Nemerson co-inventor Konigsberg, that:

in June 1987, it was difficult for one of ordinary skill in the art to assemble partial clones into a single a single nucleotide molecule. (*Nemerson Exhibit 2031.*) In this case, one would have had to assemble at least three of five partial clones to obtain a single nucleotide molecule encoding human tissue factor.

[16] A blanket citation to evidence is not acceptable. *E.g.*, *In re Swartz*, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000); *Clintec Nutrition Co. v. Baxa Corp.*, 44 USPQ2d 1719, 1723 n.16 (N.D. Ill. 1997) (failure to cite specific pages in a multipage exhibit). This practice is objectionable in part because it attempts to enlist the Board in fleshing out the omitted details of Nemerson's argument. It also imposes on Scripps, which must guess at the facts to be rebutted. This improper briefing technique would be a sufficient reason to dismiss the motion.

[213] Dr. Konigsberg stated his conclusion [2031, ¶ 5] that:

At the time the priority applications were filed, June 25, 1987, and March 31, 1987, one of ordinary skill in the art in the cloning field would not have been able to create an isolated DNA segment coding for a soluble or full-length human tissue factor protein by reading and following the specification of either the '047 application or the '103 application, without undue experimentation.

[214] Dr. Konigsberg explains that the procedure outlined in Scripps' 931 patent [FN21] is so difficult that now one of skill would use an overlapping polymerase chain reaction [PCR], a technique unavailable in June 1987, instead [2031, ¶¶ 6 & 10].

[215] Scripps counters (Paper 57 at 13) that PCR was available to one of ordinary skill in early 1987.

[216] On cross examination, Dr. Konigsberg indicated that PCR was commercially developed by 1990 [3036 at 32:20-22].

[217] The 931 patent issued from an application filed in 1992 [2031, ¶ 4].

Enablement is determined as of the application

filing date. *In re Brana*, 51 F.3d 1560, 1566 n.19, 34 USPQ2d 1436, 1441 n.19 (Fed. Cir. 1995). Nemerson directs us to no evidence of what one skilled in the art would have appreciated about the sufficiency of the enablement of the subject matter of Scripps ' 931 patent claims in 1992. For instance, we have no indication that one skilled in the art would not have appreciated that it would be better to use PCR by 1992. If anything, the ***1043** declaration of Dr. Konigsberg read together with his cross examination testimony would support a finding that one skilled in the art would have been able, and would have known to prefer, to make the claimed invention using PCR by 1990.

[218] Nemerson further argues (Paper 40 at 9) that Scripps had not made a single nucleotide molecule encoding hTF as of June 1987 or even as of 1988.

There is no requirement that Scripps have actually reduced the invention to practice before filing an application. *Pfaff v. Wells Elec., Inc.*, 525 U.S. 55, 61 [48 USPQ2d 1641] (1998) (describing the proposition as "well settled"). Rather the touchstone for enablement is whether one skilled in the art would be able to make and use the claimed invention without undue experimentation.

[219] Dr. Konigsberg explains his conclusion that, in early 1987, the disclosed methodology would require undue experimentation because it would be prone to low yields requiring time-consuming, laborious repetitions to obtain enough starting material to make the claimed invention [2031, ¶ 8].

Again, the relevant date is 1992, not 1987. Moreover, assuming *arguendo* that Scripps' disclosed process is laborious and time-consuming, that fact alone would not render the experimentation involved undue. Indeed, if the protocols at the critical date were routinely difficult, then the proper focus is on the guidance provided in the disclosure rather than the inherent difficulty of the protocols. *PPG Indus. Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996). While Scripps also argued that its specification provided alternative methods for making the claimed invention, we need not reach the alternatives.

For the reasons provided above, Nemerson preliminary motion 5 is DENIED.

Nemerson preliminary motion 6: attacking the patentability of Scripps' 931 patent claims for nonjoinder

[220] Nemerson argues (Paper 41 at 2) that Scripps' 931 patent claims are unpatentable under 35 U.S.C. 116 [FN22] for failure to name Yale Nemerson as a co-inventor.

[221] Nemerson requests (Paper 41 at 2) in the alternative that Dr. Nemerson be added as a joint inventor to the 931 patent. [FN23]

[222] Nemerson does not distinctly address Scripps 931 patent claims separately.

Failure to name an inventor will render a claim unpatentable. Since inventors need not contribute to every claim, inventorship must be determined on a claim-by-claim basis. First we construe the claims and then we assess the contribution to each claim. Conception is the touchstone of inventorship. *Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Comm'n*, 383 F.3d 1352, 1381-82, 72 USPQ2d 1609, 1630 (Fed. Cir. 2004). One does not qualify as a joint inventor merely by assisting the actual inventor: there must be a participation in the conception itself. *Bd. of Educ. ex rel. Bd. of Trs. of Fla. State Univ. v. Am. Bioscience, Inc.*, 333 F.3d 1330, 1338, 67 USPQ2d 1252, 1257 (Fed. Cir. 2003).

We construed claim 1 above to require at least an aqueous solution with a soluble hTF protein having at least residues 1-219, but less than full-length hTF. Since Nemerson does not address the added limitation of claim 2, we understand Nemerson's argument to address only claim 1.

[223] Nemerson argues (Paper 41 at 16) that Dr. Nemerson was a joint inventor of the Scripps invention with Scripps' Dr. Edgington because:

a collaboration existed between Nemerson and Edgington to generate mutually available monoclonal antibodies immunoreactive with tissue factor.

We note that 931 claim 1 is directed to an aqueous composition of a soluble fragment of hTF, not to monoclonal antibodies immunoreactive with hTF.

[224] Nemerson further argues (Paper 41 at 17) that:

Edgington made at least three separate requests of Nemerson for highly purified human brain tissue factor (which SCRIPPS ***1044** did not make themselves until May of 1986). Nemerson responded to each request by providing the brain tissue factor, once in December 1985 and twice in early 1986.

[225] Scripps admits that it requested and received purified full-length hTF from Dr. Nemerson and his associates (Paper 58 at 5).

[226] Nemerson further argues (Paper 41 at 17) that:

the tissue factor provided by Dr. Nemerson integrally advanced the inventive efforts of SCRIPPS with respect to the conception of the invention of the Count.

We note that the conception of the count is not at stake in Nemerson's preliminary motion, which asks for a judgment of unpatentability against Scripps' claims. Indeed, Nemerson's motion was filed pursuant to 37 C.F.R. § 1.633(a) (2003), which specifically bars the filing of motions alleging derivation of the count. § 1.633(a)(2).

[227] Nemerson further argues (Paper 41 at 18, citations omitted) that:

conception of the DNA molecule requires identification and possession of the molecule at the very least. Nemerson in providing the protein which the DNA encodes, contributed to SCRIPPS the means to identify and possess the DNA molecule.

We note that the claimed invention is not the DNA molecule.

[17] At the risk of prejudicing Scripps by trying to divine the argument Nemerson wants to make, it could be that Nemerson means to argue that without the full-length hTF protein, which Scripps initially obtained from Nemerson, Scripps would not have been able to characterize hTF protein, obtain DNA for hTF protein, and modify that DNA to express the hTF protein fragment recited in claim 1. We note that this is not an argument that Nemerson actually made. In any case, assuming that Nemerson's contribution was truly necessary for Edgington and Morrissey's conception, it does not automatically follow that Nemerson was an inventor. This case is most analogous to *American Bioscience*, in which the university contended that its contributions were necessary to the conception of the invention. Like Nemerson, the university emphasized, 333 F.3d at 1342, 67 USPQ2d at 1260, the considerable expertise and long experience of its scientists as well as their relationship to the named inventors. The court, however, held that even if it assumed the truth about the university scientists' work on related compounds, there was no evidence that they participated in the conception of what was actually claimed, 333 F.3d at 1342, 67 USPQ2d at 1261. Dr. Nemerson may have been the giant on whose shoulders Edgington and Morrissey stood, [FN24] but Nemerson has not pointed us to evidence that he contributed to the conception of the invention defined in claim 1.

For the reasons provided above, Nemerson preliminary motion 6 is DENIED.

Scripps motion to exclude

Scripps moved to exclude several Nemerson exhibits. In view of the disposition above, it has not been necessary to reach the admissibility of the cited exhibits. Consequently, the motion is DISMISSED as moot.

DECISION

DECIDED that Scripps preliminary motion 1 be DENIED;

FURTHER DECIDED that Scripps preliminary motion 2 be GRANTED such that Nemerson 262 claims 33 and 34 be held to be UNPATENTABLE;

FURTHER DECIDED that that Scripps preliminary motion 2 be DENIED with respect to Nemerson 262 claims 29-31 and 44;

FURTHER DECIDED that decision on Scripps preliminary motion 2 with respect to Nemerson 262 claims 36-39 be DEFERRED *30 days from the entry date of this decision*;

FURTHER DECIDED that Scripps preliminary motion 2 be GRANTED such that Nemerson 262 claims 36-39 be held to be UNPATENTABLE *unless* an amendment correcting only the typographical error involving "Figure I" in claim 36 is filed within *30 days from the entry date of this decision*, as provided above;

FURTHER DECIDED that Scripps preliminary motion 3 be GRANTED such that Nemerson 581 claims 15, 45, and 47 be held to be UNPATENTABLE, but otherwise DENIED;

FURTHER DECIDED that Nemerson preliminary motion 5 be DENIED;

FURTHER DECIDED that Nemerson preliminary motion 6 be DENIED;

***1045** FURTHER DECIDED that Scripps' motion

to exclude be DISMISSED as moot; and

FURTHER DECIDED that a copy of this decision be entered in the administrative record of Scripps's 5,622,931 patent and of Nemerson's 08/297,581 and 08/473,262 applications.

FN1. As part of Board efforts under the Government Paperwork Elimination Act, signatures on papers originating from the Board are being phased out in favor of a completely electronic record. Consequently, subsequent papers in this case originating at the Board will not have signatures. The parties have agreed to participate in the electronic filing pilot program, which has its own standard for party signatures.

FN2. Scripps exhibits are numbered from 3001; Nemerson exhibits, from 2001.

FN3. New rules came into effect after these motions were fully briefed and argued. Although the new rules do not compel a different result for any of these motions, in this decision we will continue to refer to the old rules for the sake of simplicity. See *Singh v. Brake*, 222 F.3d 1362, 1371,55 USPQ2d 1673, 1679 (Fed. Cir. 2000) (explaining choice of rules when there has been a nominal change in an interference rule); accord *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 n.2,56 USPQ2d 1001, 1005 n.2 (Fed. Cir. 2000) (applying old rule to patent issued under old rule, but noting result would be the same under either rule).

FN4. Paper 59 is Nemerson's opposition 1. Scripps' preliminary motions appear to have been entered into the record out of sequence.

FN5. A cDNA is a deoxyribonucleic acid polynucleotide that has been produced to lack DNA inclusions that are not involved in encoding a protein.

FN6. Neither party has attached any significance to the fact that hTF is an apoprotein, so neither do we.

FN7. See *Argyropoulos v. Swarup*,56 USPQ2d 1795, 1807 (BPAI 2000) (observing that vague statements about the level of skill are less helpful than evidence of what one of skill knew or could do).

FN8. Wands factors include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

FN9. To the extent that an argument could be made that 37 C.F.R. § 1.601(g) incorporated all of the requirements of § 112(1) by referring to 35 U.S.C. 120, we note that no such argument was made and that it would be difficult to reconcile with *Hunt*. In future cases, the issue will be moot since the new rules expressly rely on 35 U.S.C. 102(g)(1) in defining accorded benefit and constructive reduction to practice.

FN10. There are two distinct class of dependent claim problems: indefinite scope problems and administrative fee problems. The first type, of which *Attig* is typical, arises from inconsistencies within or between claims. A second type arises when a claim to one type of subject matter incorporates as a limitation a claim to a different type of subject matter, such as "A method. . .using the apparatus of claim 7." The Office treats the latter type of claim as presenting an administrative fee problem rather than a patentability problem. See *Ex parte Porter*,25 USPQ2d 1144, 1147 (BPAI 1992) (distinguishing between the two types of problems).

FN11. x/y is a common convention for indicating that claim x depends from claim y.

FN12. Nemerson clean copy of claims. Claim 29 should have been reproduced as a material fact.

FN13. Even a patentee may amend by filing a reissue application, provided the amendment complies with 35 U.S.C. 251(4). In any case, Nemerson is an applicant, not a patentee.

FN14. Ideally, obvious errors in the claims would never survive an effective ex parte prosecution. When as here they do, a party should recognize the need to correct obvious errors before the first motion is filed. The parties are required to file a clean copy of the claims and an annotated copy of the claims right at the outset of the proceeding. Among other benefits, this exercise is intended to focus each party on its claims prior to deciding what motions it will need to file.

FN15. For the same reason, both the parent and child claim are held unpatentable since, from the perspective of one skilled in the art, it is not apparent in which claim (if not both) the mistake lies.

FN16. The court also suggests that if doubt about the scope of the claim persists after consulting the intrinsic evidence, the real problem may be indefiniteness under § 112(2). *Digital Biometrics*, 149 F.3d at 1344 n.4, 47 USPQ2d at 1424 n.4.

FN17. In fact, one skilled in the art would have expected CNBr cleavage to produce a 1-210 residue fragment. CNBr cleavage does not eliminate the methionine residue. Instead, the methionine would be converted to homoserine lactone, a different amino acid residue. Thus, the resulting N-terminal fragment would have 210--not 209--residues, with the C-terminal residue of the fragment being homoserine lactone.

FN18. Although the question has not been briefed, since the claim is in product-by-process form, it is not clear why the claim would not read on naturally occurring hTF within a human body. *In re Thorpe*, 777 F.2d 695, 697,227 USPQ 964, 965-966 (Fed. Cir. 1985). We leave the question to further prosecution, if any, before the examiner.

FN19. The open-ended nature of the claim presents at least two different problems. First, since the claim is open to intermediate fragments other than those specifically disclosed, is there adequate support for the full range of intermediate fragments within the scope of the claim? Second, can the claim be construed to include chimeric, fusion, or other complexed proteins, and if so where is the support for such proteins? Scripps has not argued, and Nemerson has not had an opportunity to respond to, either of these questions so we leave them to further prosecution if any before the examiner.

FN20. Scripps provided no separate definition and none is needed to understand the term in context. *C.R. Bard, Inc. v. United States Surg. Corp.*, 388 F.3d 858, 863,73 USPQ2d 1011, 1015 (Fed. Cir. 2004).

FN21. The Federal Circuit has expressed disapproval of the practice of referring to the patent when the relevant document is the underlying .application. *In re Huston*, 308 F.3d 1267, 1270 n.1,64 USPQ2d 1801, 1802 n.1 (Fed. Cir. 2002) (holding error harmless). In the present case, the inappropriate reference has not been challenged and does not appear to make a difference, so we will continue to refer to the patent for the sake of consistency.

FN22. At 19, Nemerson urges that Scripps violated 35 U.S.C. 256 and 37 C.F.R. § 1.56. The basis for holding the claim unpatentable is found in 35 U.S.C. 102(f), see *Schulze v. Green*, 136 F.3d 786, 792,45 USPQ2d 1769, 1774-75 (Fed. Cir. 1998) (remanding for decision of § 102(f) inventorship question). Section 116 provides the basis for joint inventorship and correction of the inventorship for applications. Section 256 provides the basis for correcting the inventorship of patents. Nemerson's reference to § 1.56 is frivolous in view of what Nemerson actually argued and attempted to prove. Cf. *Bd. of Educ. ex rel. Bd. of Trs. of Fla. State Univ. v. Am. Bioscience, Inc.*, 333 F.3d 1330, 1344,67 USPQ2d 1252, 1262 (Fed. Cir. 2003) (rejecting failure to identify early collaborators as a basis for inequitable conduct).

FN23. Under the old rules, this should have been a separate motion under 37 C.F.R. § 1.634. Given the disposition on the merits, the mistake is moot.

FN24. "If I have seen further it is by standing upon the shoulders of Giants."

> Generally attributed to Isaac Newton, quoted in *In re Alappat*, 33 F.3d 1526, 1553 n.12,31 USPQ2d 1545, 1565 n.12 (Fed. Cir. 1994) (Archer, C.J., concurring in part and dissenting). The patent system, predicated as it is on "the Progress of. . .useful Arts", U.S. Const., art. I, § 8, cl. 8, presupposes building and improving on the results of others.

P.T.O. Bd.Pat.App. & Int.

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END OF DOCUMENT

EXHIBIT B

this potential contractual liability. The "garagekeeper's policy," however, expressly excluded from its coverage liability resulting from any agreement or contract by which Ramp accepted responsibility for the loss.[1] Thus, Reliance's obligation to pay only extended to those losses for which Ramp was legally liable on something other than a contract theory. In this case, unlike the previously paid damage claims, the statute of limitations for negligence had already run. Ramp could no longer have been held legally liable except by contract, and contractual liability was expressly excluded from the scope of the insurance policy. The fact that Reliance properly paid the prior claims pursuant to the legal liability provision of the policy certainly does not constitute sufficient circumstances to lull Ramp into inaction and justify its failure to discover the alleged fraud.

IV. WHO SHOULD DETERMINE COMMENCEMENT OF STATUTE OF LIMITATIONS

[6] Ramp also argues that the question of when the statute of frauds commenced to run is an issue for the trier of fact, and should not be decided by the court on a motion for summary judgment. Ramp cites to two Alabama cases holding that this issue is a question of fact which should be decided by the jury. *See Alabama Farm Bureau Mutual Casualty Insurance Co. v. Griffin*, 493 So.2d 1379 (Ala. 1986); *Wilson v. Draper*, 406 So.2d 429 (Ala.1981).

A proper reading of Alabama law, however, reveals that no such per se rule exists. If the facts regarding the discovery of the fraud are in dispute, it clearly would be up to the jury to determine when the statute of limitations commenced to run. However, "if the facts regarding the discovery issue are uncontroverted and show that the discovery occurred more than one year prior to the bringing of the suit, summary judgment is proper." *Gonzales v. U-J Chevrolet Co.*, 451 So.2d 244, 247 (Ala. 1984). Moreover, in *Sexton v. Liberty National Life Insurance Co.*, 405 So.2d 18 (Ala.1981), a case cited by Ramp in support of another proposition, the Alabama Supreme Court explicitly stated that "under certain circumstances the time of discovery of fraud can be determined as a matter of law." 405 So.2d at 21.

Thus, Alabama law allows the court to decide the statute of limitations question where the facts regarding the discovery of the fraud are not in dispute. Because we hold that Ramp should have discovered the alleged fraud at or shortly after the time it received the policy, the only facts relevant to the statute of limitations issue are whether and when Ramp received its copy of the insurance policy. These facts are uncontroverted in this case, therefore it was proper for the trial court to determine as a matter of law that the statute of limitations had already run.

AFFIRMED.

TEXAS INSTRUMENTS, INC., Appellant,

v.

UNITED STATES INTERNATIONAL TRADE COMMISSION, Appellee.

Appeal No. 85-2776.

United States Court of Appeals, Federal Circuit.

Nov. 19, 1986.

Electronic calculator patentholder brought action against foreign manufactur-

1. This section of the policy provided in pertinent part:

PART V. GARAGEKEEPER'S INSURANCE

....

C. WE WILL NOT COVER—EXCLUSIONS.

This insurance does not apply to:

1. Liability resulting from any agreement from which the insured accepts responsibility for loss.

ers for alleged unfair methods of competition and unfair acts in importation and sale of portable electronic calculators, based on manufacturers' alleged infringement of patent. The United States International Trade Commission found no infringement, and patentholder appealed. The Court of Appeals, Pauline Newman, Circuit Judge, held that total of technological changes made in imported calculators required finding of noninfringement.

Affirmed.

1. Patents ⇐226

Analysis of patent infringement entails determination of scope of claims as matter of law, and factual finding of whether properly construed claims encompass accused structure.

2. Customs Duties ⇐85(11)

Factual findings of United States International Trade Commission regarding patent infringement are reviewed to determine whether they are supported by substantial evidence. Tariff Act of 1930, § 337(c), as amended, 19 U.S.C.A. § 1337(c); 5 U.S.C.A. § 706.

3. Patents ⇐226.6, 226.7

"Literal infringement" requires that accused device embody every element of claim as properly interpreted; if claim describes combination of functions, and each function is performed by means described in specification or equivalent of such means, then "literal infringement" holds.

See publication Words and Phrases for other judicial constructions and definitions.

4. Patents ⇐167(1)

When claimed invention is novel combination of steps, all possible methods of carrying out each step of combination are not required to be described in specification.

5. Patents ⇐101(10)

When claimed invention is novel combination of steps, details of performing each step need not be included in claims unless required to distinguish claimed invention from prior art, or otherwise to specifically point out and distinctly claim invention. 35 U.S.C.A. § 112.

6. Patents ⇐237

For purposes of patent infringement, it is not required that those skilled in art knew, at time patent application was filed, of asserted equivalent means of performing claimed functions; equivalence is determined as of time infringement allegedly takes place.

7. Patents ⇐226.5

Devices that have been modified to such extent that modification may be separately patented may nonetheless infringe claims of basic patent.

8. Patents ⇐226.5, 237

Modification of accused device does not negate infringement when device has adopted features of claims or their equivalents.

9. Patents ⇐240

Subsequent improvements do not in themselves preclude finding of infringement.

10. Patents ⇐237

Prosecution history, other claims in patent, expert testimony, language of asserted claims, and pioneer status of invention may be considered in addition to specification in determining breadth of equivalents to be afforded means plus function clauses. 35 U.S.C.A. § 112.

11. Patents ⇐226.6

Determination of infringement is not made in abstract, but in context of claimed invention and accused devices.

12. Patents ⇐226.6

In determining whether there is infringement, it is entirety of technology embodied in accused devices that must be compared with patent disclosure.

13. Patents ⇐237

Equivalence of subsequently developed devices is not established by showing only accomplishment of same result.

14. Patents ⇐240

Patent for electronic calculator was not infringed by imported portable electronic calculators that used metal oxide semiconductors and embodied significant advances in chip design and integrated circuitry, notwithstanding that each individual claim clause considered separately could be within range of equivalence.

15. Patents ⇐237

In determining whether there is literal infringement due to equivalency of means that is described in specification to perform function in means clause of combination claim, or whether there is equivalency to claimed invention as whole, it must be determined whether asserted equivalent performs substantially same function in substantially same way to accomplish substantially same result.

16. Patents ⇐237

While prior art and prosecution history are necessary considerations in applying doctrine of equivalents, they do not of themselves control breadth of equivalents available under doctrine.

17. Patents ⇐237

Equivalency is judicially determined by reviewing content of patent, prior art, and accused device, and essentially redefining scope of claims.

James F. Davis, Howrey and Simon, Washington, D.C., argued for appellant. With him on the brief was Kenneth E. Krosin. Also on the brief were Melvin Sharp, Richard L. Donaldson and David V. Carlson, Texas Instruments, Inc., of Dallas, Tex.

Wayne W. Herrington, Office of the Gen. Counsel, of U.S. Intern. Trade Com'n, Washington, D.C., argued for appellee. With him on the brief were Lyn N. Schlitt, Gen. Counsel and Michael P. Mabile, Asst. Gen. Counsel.

Before DAVIS, Circuit Judge, COWEN, Senior Circuit Judge, and NEWMAN, Circuit Judge.

PAULINE NEWMAN, Circuit Judge.

In this action brought under section 337 of the Tariff Act of 1930 as amended, 19 U.S.C. § 1337, Texas Instruments, Inc. ("TI") appeals the final decision of the United States International Trade Commission. The Commission held that there was no statutory violation in that TI's U.S. Patent No. 3,819,921 (" '921 patent") was not infringed by certain imported calculators, and that there was no industry in the United States practicing an invention covered by any claim of the '921 patent.[1] We affirm the decision of non-infringement, and thus do not reach the issue of whether there was injury to a domestic industry.

Commission Proceedings

Texas Instruments alleged unfair methods of competition and unfair acts in the importation and sale of certain portable electronic calculators, based on the infringement of claims 1, 2, 6, 7, 30, 37, 41 and 53 of the '921 patent, and that the effect or tendency of the unfair methods and acts was to destroy or substantially injure an efficiently and economically operated industry in the United States. The Commission ordered an investigation. 49 Fed.Reg. 29,162 (1984). Twenty-one respondents were named. For details as to the parties and the proceedings, reference is made to the Commission's decision, familiarity with which is presumed. Three respondents settled with TI during the

1. *In re Certain Portable Electronic Calculators,* Inv. No. 337-TA-198, USITC Pub. No. 1732 (July 1985).

course of the proceedings, and respondents Nam Tai Electronics Co. Ltd., International Merchandising Associates Hong Kong, and Enterprex appeared at the hearing. Nam Tai subsequently settled with TI, taking worldwide licenses to all of TI's calculator patents including the '921 patent.

In the initial determination of April 18, 1985, the administrative law judge ("ALJ") considered first the defense of patent invalidity under 35 U.S.C. §§ 103 and 112, and held that the claims at issue had not been proven invalid, stating: "The presumption of validity afforded those claims under 35 U.S.C. § 282 remains unrebutted and in full effect." The Commission affirmed, and this aspect of the decision has not been appealed.

The ALJ held that TI had not sustained its burden of proving that any of the patent claims was infringed by any of the imported calculators, and that because "complainant does not produce calculators in accordance with the claims in issue of the '921 patent, no domestic industry exists." The Commission adopted these determinations. None of the respondents participated in this appeal. The Commission is the sole appellee, and appears to defend the merits of its decision.

A.

The '921 patent entitled "Miniature Electronic Calculator" was issued on June 25, 1974 to inventors Jack S. Kilby, Jerry D. Merryman and James H. Van Tassel, assignors to Texas Instruments. The '921 patent derives, through a series of continuation applications, from application Serial No. 671,777 filed September 29, 1967. It represents a pioneering invention, for which the inventors and TI have been recognized. The prototype calculator was accepted for the permanent collection of the Smithsonian's Museum of History and Technology. Patent claim 1 is representative:

1. A miniature, portable, battery operated electronic calculator comprising:

a. input means including a keyboard for entering digits of numbers and arithmetic commands into said calculator and generating signals corresponding to said digits and said commands, the keyboard including only one set of decimal number keys for entering plural digits of decimal numbers in sequence and including a plurality of command keys;

b. electronic means responsive to said signals for performing arithmetic calculations on the numbers entered into the calculator and for generating control signals, said electronic means comprising an integrated semiconductor circuit array located in substantially one plane, the area occupied by the integrated semiconductor array being no greater than that of the keyboard, said integrated semiconductor circuit array comprising:

i. memory means for storing digits of the numbers entered into the calculator,

ii. arithmetic means coupled to said memory means for adding, subtracting, multiplying and dividing said numbers and storing the resulting answers in the memory means, and

iii. means for selectively transferring numbers from the memory means through the arithmetic means and back to the memory means in a manner dependent upon the commands to effect the desired arithmetic operation;

c. means for providing a visual display coupled to said integrated semiconductor circuit array and responsive to said control signals for indicating said answer; and

d. the entire calculator including keyboard, electronic means, means for providing a visual display, and battery being contained within a "pocket sized" housing.

The specification contains a detailed description of the then preferred means of performing each step of the claims. In the

seventeen years between the first filing of the patent application and filing of the complaint with the Commission, each such means has undergone technological advance. TI asserts that the means used in the accused calculators perform the functions that are specifically set forth in the '921 claims, and that by correct claim interpretation these claims are infringed because the means used in the accused calculators are substantially the same as, or equivalent to, the means illustrated in the specification.

The Commission adopted the ALJ's extensive findings and conclusions, wherein the ALJ construed the claims in light of the specification and found no claim infringed, either literally or in terms of the doctrine of equivalents.

TI argues that substantial evidence does not support the finding of non-infringement, in that the invention as embodied in the accused calculators is fundamentally the same as that of the '921 claims, that the '921 patent represents the giant step in the development of semiconductor technology and integrated circuitry on which is based the entire industry of hand-held calculators, and that the claims are not restricted to the preferred embodiments as they existed at the time the patent application was filed.

TI points to the established law that it is not necessary that the specification have described or that the inventors have foreseen each specific means now used to perform each of the functions of the claims. TI emphasizes that this basic patent on a pioneering invention is entitled to be interpreted broadly, and indeed this proposition is long-established, *see, e.g., Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 415, 28 S.Ct. 748, 749–50, 52 L.Ed. 1122 (1908).

[1, 2] Analysis of patent infringement entails two inquiries: determination of the scope of the claims, as a matter of law; and the factual finding of whether properly construed claims encompass the accused structure.[2] *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 1282, 230 USPQ 45, 46 (Fed.Cir.1986); *Caterpillar Tractor Co. v. Berco, S.P.A.*, 714 F.2d 1110, 1114, 219 USPQ 185, 187 (Fed.Cir.1983). This analytical framework applies whether claims are asserted to be infringed literally or by application of the doctrine of equivalents.

[3, 4] Literal infringement requires that the accused device embody every element of the claim as properly interpreted. *Mannesmann*, 793 F.2d at 1282, 230 USPQ at 46; *Stewart-Warner Corp. v. City of Pontiac*, 767 F.2d 1563, 1570, 226 USPQ 676, 681 (Fed.Cir.1985). If the claim describes a combination of functions, and each function is performed by a means described in the specification or an equivalent of such means, then literal infringement holds. *See D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1575, 225 USPQ 236, 239 (Fed.Cir. 1985). This prescription derives from 35 U.S.C. § 112 paragraph 6:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The statute thus provides, and extensive judicial analysis has reinforced, that when the claimed invention is a novel combination of steps, all possible methods of carrying out each step of the combination are not required to be described in the specification. Correctly construed claims cover "equivalents of the described embodiments". *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 862, 226 USPQ 402, 408 (Fed.Cir.1985), *cert. denied*, — U.S.

2. Factual findings of the Commission are reviewed to determine whether they are supported by substantial evidence. 19 U.S.C. § 1337(c); 5 U.S.C. § 706. Legal conclusions are reviewed for correctness.

——, 106 S.Ct. 1197, 89 L.Ed.2d 312 (1986); *see also Palumbo v. Don-Joy Co.*, 762 F.2d 969, 974, 226 USPQ 5, 8 (Fed.Cir.1985); *D.M.I.*, 755 F.2d at 1579, 225 USPQ at 238.

[5] The purpose is to grant the inventor of a combination invention a fair scope that is not dependent on a catalogue of alternative embodiments in the specification. This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification. *Palumbo*, 762 F.2d at 977, 226 USPQ at 10. The details of performing each step need not be included in the claims unless required to distinguish the claimed invention from the prior art, or otherwise to specifically point out and distinctly claim the invention. 35 U.S.C. § 112 paragraph 2; *In re Lundberg*, 244 F.2d 543, 547–48, 113 USPQ 530, 534 (CCPA 1957); *In re Arbeit*, 206 F.2d 947, 958, 99 USPQ 123, 131–32 (CCPA 1953).

These principles are not unlimited in their application, but reflect the equitable concept that claims should be read in a way that avoids enabling an infringer to "practice a fraud on a patent." *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605, 608, 70 S.Ct. 854, 856, 94 L.Ed. 1097, 85 USPQ 328, 330 (1950). It has long been recognized that the range of permissible equivalents depends upon the extent and nature of the invention, and may be more generously interpreted for a basic invention than for a less dramatic technological advance. *Continental Paper Bag Co.*, 210 U.S. at 414, 28 S.Ct. at 749; *Miller v. Eagle Manufacturing Co.*, 151 U.S. 186, 207, 14 S.Ct. 310, 318–19, 38 L.Ed. 121 (1894). The questions of claim interpretation raised in this case turn on the issue of the breadth of equivalents to which the claims are entitled. As in many aspects of patent law, the legal conclusions are intertwined with, and depend upon, the technological facts.

[6] It is not required that those skilled in the art knew, at the time the patent application was filed, of the asserted equivalent means of performing the claimed functions; that equivalence is determined as of the time infringement takes place. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1581, 224 USPQ 409, 417 (Fed.Cir.1984); *see also American Hospital Supply Corp. v. Travenol Laboratories, Inc.*, 745 F.2d 1, 8, 223 USPQ 577, 583 (Fed.Cir.1984) ("the Commission erred in determining equivalence at the time of invention without regard to subsequent developments in the art"). Technological "embellishment" made possible by the patent's disclosure "does not allow the accused [device] to escape the 'web of infringement' ". *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1365, 219 USPQ 473, 483 (Fed.Cir.1983) (quoting *Bendix Corp. v. United States*, 600 F.2d 1364, 1382, 220 Ct.Cl. 507, 204 USPQ 617, 631 (1979)).

[7, 8] Devices that have been modified to such an extent that the modification may be separately patented may nonetheless infringe the claims of the basic patent. *See Atlas Powder*, 750 F.2d at 1580, 224 USPQ at 417 (infringement will be found where the material features of the patent have been appropriated, even when these features have been patentably improved). Similarly, the modification of an accused device does not negate infringement when that device has adopted the features of the claims or their equivalents. *See Radio Steel & Manufacturing Co. v. MTD Products, Inc.*, 731 F.2d 840, 847–48, 221 USPQ 657, 663–64 (Fed.Cir.), *cert. denied*, 469 U.S. 831, 105 S.Ct. 119, 83 L.Ed.2d 62 (1984) (modification of feature to perform equivalent function held as infringement, as is appropriation of patented feature to perform an additional function); *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482, 221 USPQ 649, 653 (Fed.Cir.), *cert. denied*, 469 U.S. 924, 105 S.Ct. 306, 83 L.Ed.2d 240 (1984) (quoting *McCullough Tool Co. v. Well Surveys, Inc.*, 343 F.2d 381, 402, 145 USPQ 6, 22 (10th Cir.1965),

cert. denied, 383 U.S. 933, 86 S.Ct. 1061, 15 L.Ed.2d 851 (1966) ("infringement cannot be avoided by the mere fact that the accused device is more or less efficient or performs additional functions")).

TI argues that the Commission required too narrow a construction of the '921 patent claims, contrary to this body of precedent, so that the Commission in effect limited the claims to the means that were illustrated in the specification. As stated in *D.M.I.:*

> To interpret "means plus function" limitations as limited to a particular means set forth in the specification would be to nullify the provision of § 112 requiring that the limitation *shall* be construed to cover the structure described in the specification *and* equivalents thereof. Patentees are required to disclose in the specification some enabling means for accomplishing the function set forth in the "means plus function" limitation.

755 F.2d at 1574, 225 USPQ at 238 (emphasis in original). Pertinent is the court's holding that

> there is and can be no requirement that applicants describe or predict every possible means of accomplishing that function.

Id. TI asserts that the accused devices perform all the steps of the claims, and that the detailed means by which these steps are carried out, where not described or predicted by the patentees, are the same as or equivalent to the means described in the specification.

The ALJ considered each step of the claims, and made extensive findings as to the structure and operation of the accused calculators in comparison with that described in the '921 specification. The ALJ's findings on the structure of the various devices are generally uncontroverted on this appeal, but his findings as to their operation, as well as his construction of the claims, are contested as is the conclusion of noninfringement.

In brief summary, either the ALJ found, or it was uncontested, that each of the accused calculators was a miniature, portable, battery operated device contained within a "pocket-sized" housing (preamble and clause d of claim 1); having a keyboard for entering digits of numbers and arithmetic commands into the calculator (clause a); an integrated semiconductor circuit located in substantially one plane and having memory, arithmetic, and transfer means (clause b and subclauses i, ii, and iii); and a visual display (clause c). The ALJ found that each of the functions of clauses a, b, and c was performed in the accused devices by a means that was not described in the '921 patent, and that each such means was not equivalent to the means shown in the specification. Although we conclude that substantial evidence did not support each such determination of non-equivalence as to each claim clause considered separately, we conclude that the accused devices do not infringe properly construed claims when the invention and the accused devices are viewed as a whole.

The ALJ's analysis of each "means" clause is pertinent to this determination:

Clause a—Input Means

The keyboard input means of the '921 patent, described in claim 1 as "including only one set of decimal number keys", was distinguished from the prior art decade-type keyboards during prosecution before the Patent Office. It was uncontroverted that the prior art described no calculator keyboard that functioned with a single set of decimal keys.

All of the accused calculators have the claimed "one set of decimal number keys". TI argues that this distinction is fundamental to its design of a miniature calculator, and is the only critical limitation to the input means, whereas the specific mode of internal operation of the keyboard is not limited to that illustrated in the specification.

The '921 specification describes a mechanism for the keyboard operation whereby

pressure on a key causes a conductive layer on the underside of the key to contact and short circuit conductive strips lying underneath, to produce a unique binary signal that is encoded and transmitted. An alternative embodiment is described having a conductive pattern wherein signal encoding is accomplished by the calculator memory logic. The keyboard encoder, a separate invention of Jack S. Kilby and James H. Van Tassel, is patented as U.S. Patent No. 3,696,411, the entire disclosure of which is incorporated by reference into the '921 patent.

Clause a of Claim 1 is specific to a keyboard input means for entering digits and commands and generating signals corresponding thereto. TI observes that the prosecution history does not limit the keyboard input means beyond the limitation to one set of decimal keys, which the accused keyboards all have. Experts on both sides agreed that the keyboards of the accused devices and of the '921 specification entered digits and commands and generated corresponding binary signals, but by a different internal mechanism. The accused keyboards use a scanning matrix encoder, which scans the keyboard at clock intervals in order to determine which key is depressed. Scanning matrix systems are described in Caudel and Raymond U.S. Patent No. 4,021,656, entitled "Data Input for Electronic Calculator or Digital Processor Chip", filed November 19, 1974 and issued May 3, 1977. This patent, assigned to Texas Instruments, is not asserted in this action.

The ALJ found that in a scanning matrix system the keyboard does not generate unique signals corresponding to digits and commands, and thus that the keyboard systems are not equivalent because they do not operate in substantially the same way. TI asserts that this finding is not supported by substantial evidence and reflects incorrect claim construction as a matter of law. TI asserts that claim clause a reads literally on the accused keyboards and that the internal operation of the keyboard is not material because the claimed invention lies in the "operation of the keyboard in the calculator combination to operate a unique signal for each key", not in the details of each step. Inventor Kilby described the scanning matrix as a "new invention", but testified that there is no change in the elements of the calculator:

> In all cases the elements of the calculator remain basically the same, although the costs have been significantly reduced. Most of these reductions have come about because of economies of scale in production and a move to lower cost labor areas. In other cases new inventions have contributed to the reduction in cost. An example of this would be in the keyboard. As the cost of logic was reduced, it became economically desirable to reduce the interconnections required for the chip at the expense of increased logic. The scanning keyboard is one example of this practice [clause a], while another can be found in the current means of driving the display [clause c]. Neither change has any impact on the operation of the calculator. Depressing the "2" key still sends a unique signal meaning "2" to the calculator. The calculator would be useless if it did not.

TI argues that the Commission made a fundamental error in claim construction by requiring that the means of performing the input be technologically as well as functionally identical. TI states that the Commission erroneously required scientific equivalence of the keyboards' internal operations. TI emphasizes that the invention of the '921 patent lies in the claimed combination, that the essential elements of the invention are contained in the claims, and that the accused devices also contain these elements. TI argues that the Commission erred as a matter of law in limiting the '921 claims to the specific input means illustrated in the specification, and then by determining absence of infringement on the basis of this limitation.

Clause b—Electronic Means

The "electronic means" is claimed as an "integrated semiconductor circuit array", a phrase coined by the inventors, for "performing arithmetic calculations on the numbers entered into the calculator and for generating control signals". The claims require that the array be located in substantially one plane, and be no larger than the keyboard. The specification shows an array of four integrated semiconductor circuits, three integrated semiconductor shift registers, and two resistors, interconnected by printed conductors located in one plane on an insulating substrate. An alternative embodiment in the specification, and claimed specifically in claim 2, locates the array on a single semiconductor wafer.

The integrated semiconductor array provides the logic of the calculator, performing the arithmetic, memory, and transfer functions set forth in sub-clauses i, ii, and iii of clause b. The specification describes each integrated circuit, in detail, as having a series of interconnected gates or logic circuits, constructed of, *inter alia*, bipolar transistors. The shift registers also use bipolar transistors. The shift register is the subject of a separate TI patent of Jerry D. Merryman entitled "Information Transfer System", U.S. Patent No. 3,573,754, incorporated by reference into the '921 disclosure.

The ALJ held that the "integrated semiconductor circuit array" of the '921 claims was limited to "a plurality of distinct, circuit structures or components that are electrically interconnected, each individual circuit structure or component of the array, whether the array is on a wafer or a plurality of wafers, having its own functional identity and separate in space"; that is, the specific structure described in the '921 specification. The ALJ found that the accused calculators all use a single integrated circuit, and concluded that there was neither identity nor equivalence of means for performing the electronic function.

TI asserts that this holding is incorrect as a matter of claim construction, and also that the finding of non-equivalence is not supported by substantial evidence. TI argues that as illustrated in the specification the electronic means may be an arrangement of four integrated semiconductor circuits and three integrated semiconductor shift registers in one plane smaller than the keyboard or, alternatively, a single wafer containing on it the four circuits and three shift registers. TI describes the corresponding electronic means in the accused devices as a single semiconductor wafer or chip using integrated circuitry. All perform arithmetic calculations and generate control signals using integrated circuitry. TI points out that the prosecution history of the '921 claims does not require the restricted definition of "integrated semiconductor circuit array" that was imposed by the ALJ.

All parties agree that there have been many improvements in the miniaturization of integrated circuitry and advances in semiconductor technology. Witnesses on both sides agreed that the electronic means of the accused devices and that described in the '921 patent use integrated semiconductor circuitry. TI argues that the difference between the semiconductor circuitry of the accused devices and the semiconductor circuit array of the '921 patent is "simply size", that both are located in substantially one plane as the claims require, and perform the arithmetic, memory and transfer functions of the claims.

The ALJ also found that because the '921 patent specification describes only bipolar transistors, the use of metal oxide semiconductor ("MOS") transistors in the accused calculators serves to avoid infringement. The '921 specification does not mention metal oxide semiconductors, but neither does it limit the semiconductor to the bipolar form. There was unrebutted testimony by inventor Merryman that metal oxide semiconductors were known at the time the '921 invention was made, and were rejected as the best mode then known "since MOS was not yet reliable". Respon-

dents' expert testified that MOS and bipolar transistors are made from the same basic semiconductor materials, but that MOS transistors have the advantage of not requiring a constant flow of current for logic functions as do bipolar. It was also uncontroverted that MOS transistors have now replaced bipolar transistors as the switch of choice in the circuitry of miniaturized calculators. TI argues that the claims of the '921 patent were erroneously construed as limited to bipolar transistors, because the two types of transistors "function in the same way in calculator digital circuits, i.e., as electronic switches", and that MOS transistors were a known alternative to bipolar transistors, as demonstrated by U.S. Patent No. 3,453,601 entitled "Two Speed Arithmetic Calculator", assigned to Philco Ford, filed October 18, 1966 and issued July 1, 1969. TI asserts that the "invention of the '921 patent resides in the achievement of a threshold size and power consumption; transistors which meet these threshold requirements are interchangeable".

The ALJ found that TI's prototype calculator "was built with bipolar or discrete technology using discretionary wiring". TI argued the interchangeability of the electronic means on the basis of a Japanese publication describing a desk calculator, and on the basis of the ready conversion of bipolar circuitry to MOS. The ALJ found that MOS and bipolar transistor technologies are not interchangeable because of differences in surface area and power consumption. The ALJ thus found the electronic means of the accused calculators not equivalent to that described in the '921 specification or within the scope of the '921 claims.

Clause c—Display Means

The display means receives information from the keyboard and the electronic means and converts it into a visual display. The visual display is not limited in claim 1 to any particular form, but is shown in the specification as a thermal printer with semiconductor heater elements which are selectively energized to create dots on a tape in the form of numbers or symbols. The accused devices all use liquid crystal displays ("LCD").

The thermal printer is specifically claimed in this overall combination in claim 4 of the '921 patent, not here asserted. The thermal printer is separately patented by TI in U.S. Patent No. 3,501,615 entitled "Integrated Heater Element Array and Drive Matrix", inventors Jerry D. Merryman and Edward M. Ruggiero, incorporated by reference in the '921 specification.

The ALJ construed the scope of clause c to be limited to the thermal printer, and held that the LCDs of the accused devices are not the same as or equivalent to the thermal printer. As found by the ALJ, an LCD consists of two glass electrode-coated sheets between which is sealed a liquid crystalline material; the application of voltage between the electrode coatings effects the arrangement of molecules in the material to form visible characters. The ALJ distinguished the thermal printer from the LCD in its method of operation, finding that the printer produces a hard copy requiring a continuous input of paper, while the LCD has a continuously pulsed line segment display. Inventor Kilby testified that he had never seen a thermal printer on either a thin "credit card" or a solar powered calculator. On the basis of the inventor's testimony and that of the respondents' technical expert, the ALJ concluded that the greater size and power requirements of the thermal printer precluded equivalence with the LCD.

TI argues that the ALJ applied an incorrect standard by focusing on the differences in operation, and that the correct standard was whether the LCD served as a visual display means in the claimed combination. Inventor Kilby testified that the use of a LCD was merely a functional substitution of one display means for another, and that after the LCD was devel-

oped its replacement of the thermal printer was a matter of ordinary skill. Kilby testified that cathode ray tubes, "nixie" tubes, light emitting diodes, and LCDs are all examples of visual displays, and that:

> In their physical embodiments they have nothing in common, but all are readable by the eye. So is a printed output. All are visual displays and fully within the '921 patent.

TI argues that the ALJ erred in limiting claim 1 to the thermal printer specifically claimed in claim 4, citing *Palumbo*, 762 F.2d at 977, 226 USPQ at 10, and the "immutable and universally applicable" rule of claim differentiation of *D.M.I.*, 755 F.2d at 1574, 225 USPQ at 239. The Commission argues that the ALJ did not read the limitation of claim 4 into claim 1, but rather interpreted the visual display means of claim 1 as limited to the thermal printer described in the specification and its equivalents. The Commission asserts that none of the accused devices uses any kind of printer, and that "[i]t is manifest that an LCD display is not equivalent to the '921 thermal printer".

The Invention as a Whole

The '921 patent claims are all written in the form appropriate to a multi-step combination invention, wherein each step of a novel combination is described in terms of its function in the total combination. Each such function is presented in the "means" form contemplated by 35 U.S.C. § 112 paragraph 6, and each such means is illustrated in the specification in accordance with the statutory requirement under 35 U.S.C. § 112 paragraph 1 to set forth the best mode then known to the inventors.

[9] TI correctly states and the ALJ so found, that every function described in the '921 patent claims is performed by the accused calculators. There was not substantial evidence to the contrary. The ALJ, finding that each of the means of performing these functions in the accused calculators embodied, to varying degrees, new or improved technology over that known or developed at the time the '921 patent application was filed, held that the means of each step was not equivalent to that shown in the specification, and thus found the claims not infringed. As a matter of law, subsequent improvements do not in themselves preclude a finding of infringement. *Atlas Powder*, 750 F.2d at 1580–81, 224 USPQ at 417; *Hughes Aircraft*, 717 F.2d at 1365, 219 USPQ at 483.

We conclude that the ALJ interpreted the claims too narrowly when he, in effect, limited each means to the embodiment shown in the specification. As stated in *D.M.I.*:

> The statute, § 112–6, was written precisely to avoid a holding that a means-plus-function limitation must be read as covering only the means disclosed in the specification.

755 F.2d at 1574, 225 USPQ at 238. *See also Radio Steel*, 731 F.2d at 848, 221 USPQ at 663 (quoting *Lockheed Aircraft Corp. v. United States*, 553 F.2d 69, 82, 213 Ct.Cl. 395, 193 USPQ 449, 460 (1977) ("where a claim sets forth a means for performing a specific function, without reciting any specific structure for performing that function, the structure disclosed in the specification must be considered, and the patent claim construed to cover both the disclosed structure and equivalents thereof")).

[10, 11] As an aid in determining the breadth of equivalents to be afforded means plus function clauses under section 112, the prosecution history, the other claims in the patent, expert testimony, and the language of the asserted claims may be considered in addition to the specification. *King Instrument*, 767 F.2d at 862, 226 USPQ at 408; *Palumbo*, 762 F.2d at 975, 226 USPQ at 8. The pioneer status of the invention also requires consideration. *Continental Paper Bag*, 210 U.S. at 415, 28 S.Ct. at 749–50. As explained in *Claude Neon Lights, Inc. v. E. Machlett & Son*, 36

F.2d 574, 576 (2d Cir.1929) (L. Hand, J.), *cert. denied*, 281 U.S. 741, 50 S.Ct. 347, 74 L.Ed. 1155 (1930):

> [T]he claim is not to be taken at its face—however freely construed—but its elements may be treated as examples of a class which may be extended more or less broadly as the disclosure warrants, the prior art permits, and the originality of the discovery makes desirable.
>
> * * * * * *
>
> The usual ritual, ... that the same result must follow by substantially the same means, does not help much in application; it is no more than a way of stating the problem. Any decision is therefore bound to have an arbitrary color, as in all close cases of interpretation....

While the scope of patent claims under section 112 paragraph 6, is a legal determination, it is not devoid of equitable considerations, particularly when determining the breadth of "means" claims on complex and rapidly-evolving technologies. Thus it has long been recognized, as affirmed in *Graver Tank*, 339 U.S. at 609, 70 S.Ct. at 856–57:

> Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum. It does not require complete identity for every purpose and in every respect. In determining equivalents, things equal to the same thing may not be equal to each other and, by the same token, things for most purposes different may sometimes be equivalents. Consideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform.

However, this does not mean that there is no limit on changed means of performing a claimed function, such that literal infringement can never be avoided. There must be outer boundaries to the scope of these rules, as for most rules, when the factual situation strains their rote application and requires a fresh look at the rules in the new context in which they are presented. There is no abstract guide to determining when a modified device crosses the boundary with respect to the reasonable scope of patent claims. Indeed, the determination of infringement is not made in the abstract, but in the context of the claimed invention and the accused devices. *Graver Tank*, 339 U.S. at 607, 70 S.Ct. at 855–56; *Amstar Corp. v. Envirotech Corp.*, 730 F.2d at 1481–82, 221 USPQ at 653.

TI argues eloquently that consideration of the breadth of equivalents for its pioneering invention requires emphasis on the function of each step of the combination as claimed, and not on the specific means of performing each step that is set forth in the patent's disclosure. Before the Commission TI asserted that the '921 invention created a totally new market for electronic calculating devices, that there is nothing remotely similar in the prior art, and that "[t]his portable, miniature, battery operated calculator is a dramatic advance deserving pioneer status." Indeed, we agree.

TI asserts that the correct interpretation of the '921 claims does not limit the claims to the means described in the specification and to those equivalents that are operationally identical, but extends to include corresponding means that perform substantially the same function in substantially the same way to obtain the same result within the combination of the claims. We agree, and as we have stated, we conclude that when each changed means is considered separately, as part of the overall device as described by the inventors, substantial evidence may not support the finding that the resultant device is not an infringement of the '921 claims. However, this is not the situation before us.

[12] Mindful of the admonition so often urged by us, it is the claimed invention as a whole that must be considered in determining whether there is infringement by the accused devices also considered as a whole.

It is not appropriate in this case, where all of the claimed functions are performed in the accused devices by subsequently developed or improved means, to view each such change as if it were the only change from the disclosed embodiments of the invention. It is the entirety of the technology embodied in the accused devices that must be compared with the patent disclosure. *D.M.I.*, 755 F.2d at 1575, 225 USPQ at 239; *see also Hughes Aircraft*, 717 F.2d at 1363–64, 219 USPQ at 482–83. Any other view distorts both the correct interpretation of the claims and their application to the accused devices.

The ALJ observed that it was not entirely clear from the record before him whether all the accused calculators embodied all of the technological changes here discussed. We have not considered the infringement status of calculators containing fewer modifications than those discussed by the ALJ, but have based our conclusion on the accused devices generally found by the ALJ. We do not pass at all on the infringement status of devices embodying less than the full combination of changes.

TI observes that in *Decca Ltd. v. United States*, 554 F.2d 1070, 210 Ct.Cl. 546, 191 USPQ 439 (1976), *confirmed in part, modified in part*, and *overturned in part*, 640 F.2d 1156, 225 Ct.Cl. 326, 209 USPQ 52 (1980), *cert. denied*, 454 U.S. 819, 102 S.Ct. 99, 70 L.Ed.2d 89 (1981), *Lockheed*, and *Hughes Aircraft*, the courts held a digital computer equivalent to an analog computer even though the digital computer was an improvement, because both performed the same function in the claimed electronic systems. By analogy, TI argues that in "fast-moving" arts infringers should not be permitted to avoid liability by arguing that the improved elements substituted in the patented combination operate in a different "way." TI asserts that to fail to find infringement under these circumstances "will emasculate electronics patents by limiting the scope of their claims to the specific embodiments disclosed in the specification."

The '921 specification describes the calculator as having the dimensions 4¼ inches by 6⅛ inches by 1¾ inches, and weighing 45 ounces, providing "a miniature portable electronic calculator of pocket-size dimensions." We agree with TI that a mere change in size due to improved miniaturization by technological advance does not in itself save the accused devices from infringement, and that the Commission erred to the extent that it construed the claims as limited to the 1967 state of the art of integrated semiconductor circuitry. Were the electronic means of clause b the only change, the record may not contain substantial evidence in support of the ALJ's finding of non-infringement. But viewing all of the modifications in the accused devices, we conclude that they reflect more than mere substitution of "an embellishment made possible by [improved] technology", as discussed in *Hughes Aircraft*, 717 F.2d at 1365, 219 USPQ at 483 (citing *Bendix*, 600 F.2d at 1382, 204 USPQ at 631); *Decca Ltd.*, 544 F.2d at 1080–81, 191 USPQ at 447–48; and *Eastern Rotorcraft Corp. v. United States*, 397 F.2d 978, 981, 184 Ct.Cl. 709, 154 USPQ 43, 45 (1967), *aff'd*, 158 USPQ 294 (Ct.Cl.1968).

To summarize the totality of changes: The input means in the '921 patent is a keyboard encoder that operates through conductive strips under the keys, whereas in the accused devices it is a scanning matrix encoder. The electronic means in the '921 patent is an integrated semiconductor array based on bipolar semiconductor technology; the accused devices use metal oxide semiconductors and embody significant advances in chip design and integrated circuitry. The display means in the '921 patent is a thermal printer, whereas the accused calculators use liquid crystal displays. Taken together, these accumulated differences distinguish the accused calculators from that contemplated in the '921 patent and transcend a fair range of equivalents of the '921 invention. Each individual difference, standing alone, could conceivably lead to a different result, by

application of this court's precedent. It is to the invention as a whole to which this same precedent directs our analysis.

The ALJ found that the technological breakthrough that made the miniature electronic calculator possible was the invention of the integrated circuit in 1958. Inventor Merryman had testified that "[s]imply making the determination that parts need to be small and interacted to fit in a pocket-sized housing does not take other than ordinary skill", but that it was the "[c]hoosing, developing and interacting, and all of those had to be done. None of those components were ready." Inventor Kilby similarly testified that "a number of new technologies [were] required" to achieve the size, cost and power objectives of the project which culminated in the '921 invention.

[13] Equivalence of the subsequently-developed devices is not established by showing only accomplishment of the same result. "[A]bstractions cannot be patented." *Sealed Air Corp. v. U.S. International Trade Commission*, 645 F.2d 976, 985, 209 USPQ 469, 477 (CCPA 1981). As stated in *Westinghouse v. Boyden Power Brake Co.*, 170 U.S. 537, 569, 18 S.Ct. 707, 723, 42 L.Ed. 1136 (1898),

> even if the patent for a machine be a pioneer, the alleged infringer must have done something more than reach the same result.

[14] We conclude that the total of the technological changes beyond what the inventors disclosed transcends the equitable limits illustrated, for example, in *Graver Tank, D.M.I., Hughes Aircraft*, and *Atlas Powder*, and propels the accused devices beyond a just scope of the '921 claims. The record before us contains substantial evidence to support the ALJ's conclusion that TI did not sustain its burden of proving infringement by the accused calculators under 35 U.S.C. § 112 paragraph 6.

B.

TI presented the alternative argument that if the claims are not deemed literally infringed in terms of 35 U.S.C. § 112 paragraph 6, they should be held infringed in terms of the doctrine of equivalents.

When literal infringement under section 112 paragraph 6 is not present the doctrine of equivalents may nevertheless apply, and thereby secure to the patentee the fair scope of the patent. *See Graver Tank*, 339 U.S. at 607–08, 70 S.Ct. at 855–56; *Hughes Aircraft*, 717 F.2d at 1361, 219 USPQ at 480. In this case, however, where the claimed functions are all performed in the accused devices, the considerations discussed in part A also apply to an infringement determination in terms of the doctrine of equivalents.

[15] Whether the issue is equivalency of a means that is described in the specification to perform a function in a "means" clause of a combination claim (*i.e.*, literal infringement), or equivalency to the claimed invention as a whole (*i.e.*, infringement by the *doctrine* of equivalents), the test is the same three-part test of history: does the asserted equivalent perform substantially the same function in substantially the same way to accomplish substantially the same result. (In the case of "means" clauses, of course, the function is that stated in the claim.) This test has been described in various ways, *see, e.g., Deller's Walker on Patents*, § 546–558 (2d ed. 1972).

In the case of literal infringement of a claim containing a "means" clause in terms of section 112 paragraph 6, the accused structure, composition, or process is compared with that described in the specification for performing the claimed function. In the case of infringement under the doctrine of equivalents, the accused structure, composition, or process is compared with the claimed invention as a whole.

The interplay between the doctrine of equivalents and the permissible scope of the claims may be limited by the prosecution history. *Builders Concrete, Inc. v. Bremerton Concrete Products Co.*, 757

F.2d 255, 258, 225 USPQ 240, 242 (Fed.Cir. 1985); *Caterpillar Tractor Co.*, 714 F.2d at 1115–16, 219 USPQ at 187–88; *see also Hughes Aircraft*, 717 F.2d at 1362–63, 219 USPQ at 481–82. There is nothing in the prosecution history to constrain the breadth of claim interpretation which TI proposes. TI is correct in its assertion that neither the prior art nor the prosecution history mandates exclusion of the accused devices from the reach of the claims.

[16] While the prior art and prosecution history are necessary considerations in applying the doctrine of equivalents, they do not of themselves control the breadth of equivalents available under the doctrine. *See Hughes Aircraft*, 717 F.2d at 1363, 219 USPQ at 482. In this case, the determination turns on the totality of change in the accused devices from that described in the '921 specification. For the reasons discussed in part *A*, the extensive technological advances in all of the claimed functions support the ALJ's finding that the accused devices are not equivalent to the claimed invention, applying the criteria of *Graver Tank*.

[17] The determination of equivalency by its nature is inimical to the basic precept of patent law that the claims are the measure of the grant. *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339, 81 S.Ct. 599, 600–01, 5 L.Ed.2d 592 (1961). The doctrine of equivalents, ubiquitous since its origin in *Winans v. Denmead*, 56 U.S. (15 How.) 330, 14 L.Ed. 717 (1853), exists solely for the equitable purpose of "prevent[ing] an infringer from stealing the benefit of an invention." *Graver Tank*, 339 U.S. at 608, 70 S.Ct. at 856. To achieve this purpose, equivalency is judicially determined by reviewing the content of the patent, the prior art, and the accused device, and essentially redefining the scope of the claims. This constitutes a deviation from the need of the public to know the precise legal limits of patent protection without recourse to judicial ruling. For the occasional pioneering invention, devoid of significant prior art—as in the case before us—whose boundaries probe the policy behind the law, there are no immutable rules. We caution that the incentive to innovation that flows from "inventing around" an adversely held patent must be preserved. To the extent that the doctrine of equivalents represents an exception to the requirement that the claims define the metes and bounds of the patent protection, we hearken to the wisdom of the Court in *Graver Tank*, that the purpose of the rule is "to temper unsparing logic" and thus to serve the greater interest of justice.

The decision of the Commission that the claims are not infringed is

AFFIRMED.

Floyd J. STANEK, Petitioner,

v.

DEPARTMENT OF TRANSPORTATION, Respondent.

Appeal No. 86–869.

United States Court of Appeals, Federal Circuit.

Dec. 3, 1986.

Former government highway engineer appealed decision of Merit Systems Protection Board affirming his removal. The